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## Dollar and Senses: Pharmaceutical Product Design is Becoming Vivid

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Dollars and Senses:  
Pharmaceutical Product Design is Becoming Vivid

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**Abstract:** Prilosec purple, Viagra blue, and Prozac green and cream: pharmaceutical product design is on the rise, and the future is even brighter. As design features come into view, protection against copying is critical to maintaining the effectiveness of these source-identifying marks. The current state of trademark law allows drug manufacturers to prevent competitors from producing similar medications with the same appearance or identifying design feature. However, while most courts have been increasingly sympathetic to product design protection, these tools are not yet being fully utilized by the pharmaceutical industry. This paper describes the current state of trademark and trade dress protection of pharmaceutical product design, such as color, shape, and flavor and provides insight into why pharmaceutical companies have yet to take full advantage of available trademark and trade dress protection.

## I. Introduction

Prilosec purple, Viagra blue, and Prozac green and cream: pharmaceutical product design is on the rise, and the future is even brighter. As design features come into view, protection against copying is critical to maintaining the effectiveness of these source-identifying marks. Trademark law increasingly permits drug manufacturers to prevent competitors from producing similar medications with the same appearance or identifying design feature. However, while most courts have been increasingly sympathetic to product design protection, these tools are not yet being fully utilized by the pharmaceutical industry.

When a drug is introduced, the manufacturer's monopoly is assured through patent protection, but once the patent expires, the market is often flooded with lower-priced versions of the same drug<sup>1</sup>produced by competitors.<sup>2</sup>In 1984, Congress introduced the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Act, facilitating the process for generic entrance into the market.<sup>3</sup>The act also served to legitimate generic pharmaceuticals; the acknowledgement that generics are considered safe and

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<sup>1</sup>Whether or not generic versions of the name brand pharmaceuticals are actually the "same" can often be a matter of dispute. The FDA requires that generic drugs be "identical, or bioequivalent to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use." <http://www.fda.gov/cder/ogd/index.htm> (last visited Mar. 3, 2003). The U.S. Supreme Court defined drugs as bioequivalent "if, when administered in equal amounts to the same individual, they reach general circulation at the same relative rate and to the same relative extent." *Inwood Labs., Inc. v. Ives Labs., Inc.*, 456 U.S. 844, 848 n.5 (1982) (citing *Remington's Pharmaceutical Sciences* 1368 (15<sup>th</sup> ed. 1975)). However, name brand pharmaceutical companies may claim that their products remain superior due to an even higher quality standard than required by the government regulator. *See American Home Products Corp. v. Chelsea Labs., Inc.*, 572 F. Supp. 278, 280 (D.N.J. 1982) *aff'd mem* 722 F.2d 730 (3<sup>rd</sup> Cir. 1983) (accepting the plaintiff-brand manufacturer's assertion that its preparation of "conjugated estrogen" is of a higher quality and held to more stringent standards than those required for a U.S.P. label).

<sup>2</sup>Generic drug companies can capture 50% of a brand manufacturer's unit sales within a year of patent expiration. Shawn Tully, *Why Drug Prices Will Go Lower*, *FORTUNE*, May 3, 1993, at 56.

<sup>3</sup>Along with offering brand name companies a patent extension to compensate for FDA regulatory delays, the Hatch-Waxman Act expedited the FDA approval process for generic equivalents by creating an abbreviated new drug application, ANDA, and allowing the generic manufacturer to use data from the original, brand drug's application. This enables generics to enter the market as soon as the brand drug's patent expires. *See Gregory J. Glover, Impact of Hatch-Waxman Goes Beyond Generics*, *NATIONAL LAW JOURNAL*, June 6, 1997, at C7.

equivalent to brand name drugs, increased public acceptance, awareness, and thus, consumption of generics. A 1998 Congressional Budget Office Study found that since the enactment of Hatch-Waxman, the generic market share rose from 18.6% to 42.6%.<sup>4</sup>Consequently, brand name pharmaceuticals rapidly lose market shares as cheaper generics are introduced. From 1991 to 1993, within one year of patent expiration, brand name drugs lost 44% of their market share on average.<sup>5</sup>More recently, Prozac sales decreased by 85% in the three months after generic competition began.<sup>6</sup>Moreover, whereas prior to Hatch-Waxman, only 35% of top selling pharmaceuticals had generic equivalents, almost all successful sellers now compete with generics.<sup>7</sup>This increase in generic competition underscores the need for brand name manufacturers to distinguish their products.

As a patent term nears expiration, manufacturers can turn their attention to a unique design to maintain sales; although generic manufacturers may reproduce drugs, they are not necessarily entitled to mimic the appearances of prescription drugs. Since 1997, the FDA has permitted manufacturers of prescription drugs to use direct-to-consumer (DTC) advertising,<sup>8</sup>and this has increased public recognition of brand names and product design. In the year 2000, pharmaceutical companies spent \$2.5 billion on such marketing in the United States,<sup>9</sup>and several promotional strategies aimed at the public have focused on appearance as well

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<sup>4</sup>This study examined drugs that comprise approximately 70% of prescription drug sales through retail pharmacies and considered drugs in the form of “easily countable units.” Melissa C. Popolillo, *Government Study Reveals Generics’ Impact on Industry*, DRUG STORE NEWS, Oct. 19, 1998, at CP20 (citing the CBO July 1998 Study, *How Increased Competition from Generic Drugs has Affected Prices and Returns in the Pharmaceutical Industry*).

<sup>5</sup>*Id.*

<sup>6</sup>*Generics Threat to Drug Firms*, BUSINESS, Apr. 21, 2002, at 12.

<sup>7</sup>Popolillo, *supra* note 4, at CP20.

<sup>8</sup>Previously, the FDA’s requirement that prescription drug ads list all of the possible side effects prevented drug manufacturers from being able to condense all of the information into a short television or radio spot. However, the changes relaxed the disclosure requirements, allowing drug manufacturers to promote their products directly to the public. See David Stout, *Drug Makers Get Leeway on TV Ads*, N.Y. TIMES, Aug. 9, 1997, at Sec. 1, p.35, column 5.

<sup>9</sup>*Pharma Brands Capture Hearts and Minds*, IMS HEALTH Global Services, at [http://www.ims-global.com/insight/news\\_story/0109/news\\_story\\_010925.htm](http://www.ims-global.com/insight/news_story/0109/news_story_010925.htm) (last visited Feb. 11, 2003).

as function.

This paper describes the current state of trademark and trade dress protection of pharmaceutical product design, such as color, shape, and flavor and provides insight into why pharmaceutical companies have yet to take full advantage of available trademark and trade dress protection. Part II discusses the growing acceptance of trade dress protection for pharmaceuticals. Part III focuses on the seismic change in trademark doctrine instituted by *Qualitex v. Jacobson Products*,<sup>10</sup> which permitted registration and protection of color per se. Part IV discusses the subsequent interpretations of *Qualitex* and suggests that other single-feature non-traditional marks may receive increased protection in light of this watershed opinion. Finally, with a few exceptions, the pharmaceutical industry overall has been hesitant to take advantage of the increasingly expansive bounds of trademark doctrine, and Part V offers possible explanations for the industry's inaction. As the breadth of trademark and trade dress protection continues to expand, protection for aspects of pharmaceutical design that identify its source should increase, as should pharmaceutical companies' interest in pursuing this protection.

## II.

### Prior Case Law on Trade Dress Protection

Courts have generally been sympathetic to claims against manufacturers of generic “look alike” pharmaceuticals. In fact, many courts affirmed manufacturers' rights to brand their products even after Congress and the FDA proclaimed their support for generic drugs in the Hatch Waxman Act. When generic drugs are produced and distributed in the same color, shape, and texture as the original, the name brand manufacturer often brings suit claiming a violation of §43(a) of the Lanham Act and violations of the relevant state unfair competition laws.<sup>11</sup> Federal unfair competition law set out in section 43(a) of the Lanham Act states:

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<sup>10</sup>514 U.S. 159 (1995).

<sup>11</sup>15 USC § 1125(a) (2002); *see, e.g.*, *American Home Products v. Chelsea Labs., Inc.*, 572 F. Supp. at 279.

Any person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which –

- (A) is likely to cause confusion, or to cause mistake, or to deceive as to the affiliation, connection, or association of such person with another person, or as to the origin, sponsorship, or approval of his or her goods, services, or commercial activities by another person, or
- (B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities,

shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.<sup>12</sup>

Federal unfair competition encompasses the torts of “unprivileged imitation” and “passing off.” Unprivileged imitation requires the trade dress in question to serve no function other than source identification, to be distinctive – either inherently or through the acquisition of secondary meaning; moreover, there must be a likelihood of consumer confusion.<sup>13</sup> Unfair competition can also be proved independently from unprivileged imitation through a showing of “passing off.”<sup>14</sup> As a result, a generic manufacturer can be held responsible for promoting illegal substitutions by pharmacists without evidence of a manufacturer's direct involvement.<sup>15</sup> Many plaintiffs have been successful in their claims of §43 violations, with some winning preliminary injunctions prior to trial.<sup>16</sup> However, despite the growing sympathy of district and appellate courts for brand name manufacturers, the Supreme Court has remained evasive. The highest court has heard only one case on trade dress infringement of look-alike drugs in more than fifty years, and its decision, which favored the

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<sup>13</sup>See, e.g., *American Home Products v. Barr Labs.*, 656 F. Supp. 1058, 1061 (D.N.J. 1987) (citing *American Greetings Corp. v. Dan-Dee Imports, Inc.*, 807 F.2d 1136, 1140 (3rd Cir. 1986) (requiring “that the feature or overall combination of features imitated is non-functional, that it has acquired secondary meaning, and that members of the consuming public are likely to confuse the source of the product bearing the imitating feature or combination with the source of the product bearing the imitated feature or combination”).

<sup>14</sup>*Marion Labs., Inc. v. Michigan Pharmacal Corp.*, 338 F. Supp. 762, 769 (E.D. Mich. 1972).

<sup>15</sup>See, e.g., *Hoffman-La Roche, Inc. v. Premo Pharm. Labs., Inc.*, 1980 U.S. Dist. LEXIS 16851, at \*41 (D.N.J. 1980).

<sup>16</sup>See *id.*; *Ross-Whitney Corp. v. Smith Kline & French Labs.*, 207 F.2d 190 (9<sup>th</sup> Cir. 1953); *McNeil-PPC, Inc. v. Granutec, Inc.*, 919 F. Supp. 198 (E.D.N.C. 1995); *Pennwalt Corp. v. Zenith Labs., Inc.*, 472 F. Supp. 413 (E.D. Mich. 1979).

manufacturer of the look-alike, was ultimately decided on a mere technicality.<sup>17</sup> Overall, the precedent on trade dress protection for pharmaceuticals sets a cautiously optimistic tone for brand name use of product design as a source-identifier.

## A. Secondary Meaning

A name brand pharmaceutical company's first hurdle in achieving trade dress protection is establishing secondary meaning for a drug's appearance.<sup>18</sup> The United States Supreme Court has defined secondary meaning as a showing that "in the minds of the public, the primary significance of a product feature or term is to identify the source of the product rather than the product itself."<sup>19</sup> However, the public need not be able to identify this source by name; the court in *CIBA-GEIGY v. Bolar Pharmaceuticals* noted that "to establish secondary meaning it is not necessary for the public to be aware of the name of the manufacturer which produces a product; rather, *it is sufficient if the public assumes that the product comes from a single though anonymous, source.*"<sup>20</sup> Secondary meaning can be established using a variety of evidence. Courts

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<sup>17</sup>*Inwood Labs.*, 456 U.S. at 856.

<sup>18</sup>It is theoretically plausible that courts could view a drug's unique color, shape and texture as inherently distinctive, thus deserving of protection without a showing of secondary meaning. However, this possibility has rarely been mentioned, and was rejected in *Florida Breckenridge, Inc. v. Solvay Pharmaceuticals, Inc.*, 1997 U.S. Dist. LEXIS 17574, at \*11-15 (S.D. Fla. 1997) (finding that while the overall appearance is distinctive and arbitrary, third party use of similar combinations weighs against a finding of inherently distinctive trade dress).

<sup>19</sup>*Inwood Labs.*, 456 U.S. at 851 n.11 (citing *Kellogg Co. v. National Biscuit Co.*, 305 U.S. 111, 122 (1938)).

<sup>20</sup>*CIBA-GEIGY v. Bolar Pharm.*, 547 F. Supp. 1095, 1113 (D.N.J. 1982), *aff'd*, 747 F.2d 844 (3<sup>rd</sup> Cir. 1984), *cert denied*, 105 S.Ct. 2678 (1985) (citing *Processed Plastic Co. v. Warner Communications, Inc.*, 675 F.2d 852, 856 (7th Cir. 1982) (emphasis added)) (finding that the blue and white opaque capsules and pink and white opaque capsules were sufficiently recognizable and had attained secondary meaning).



generally consider factors such as extensive sales of a product sold with a particular trade dress,<sup>21</sup> extensive marketing,<sup>22</sup> widespread distribution of starter kits,<sup>23</sup> and consumer surveys,<sup>24</sup> to assess whether a drug's unique appearance has achieved secondary meaning.

The ability of such factors to link a drug's trade dress with a single source has been questioned, but the Third Circuit precedent for accepting these factors remains. While the majority in the *CIBA-GEIGY* appeal agreed with the district court that the association of the drug's trade dress with the drug's brand name and manufacturer met the requirement for showing secondary meaning, the dissent dismissed these factors as "merely indicia of secondary meaning" and argued that the association "probably" served to identify only the function of the medication "(e.g., 'my blood pressure medicine')." <sup>25</sup>In a previous Third Circuit decision, *SK&F v. Premo Pharmaceutical Laboratories*, the court found that a name brand drug's appearance served to identify the drug as a particular diuretic, thus having acquired secondary meaning.<sup>26</sup> The dissent in *CIBA-GEIGY* attempts to establish that in this case, unlike in *SK&F*, an unrelated name brand drug looked similar to the name brand drug in question, thus preventing the trade dress from being identified with a

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<sup>21</sup>See *id.*; *American Home Products v. Chelsea*, 572 F. Supp. at 281 (finding that unique trade dress plus long usage, alone, can establish secondary meaning).

<sup>22</sup>See *Par Pharm., Inc. v. Searle Pharm., Inc.*, 1985 U.S. Dist. LEXIS 16648, at \*7-8 (N.D. Ill. 1985) (holding that evidence of a \$2,000,000 spent on marketing of a particular blue-colored tablet was one of several factors which made a claim of secondary meaning likely to succeed at trial); *Boehringer Ingelheim G.m.b.H v. Pharmadyne Labs.*, 532 F. Supp. 1040 (D.N.J. 1980) (ruling that marketing expenses of over \$15 million promoting both the drug's trademark and orange-colored, smoothly rounded, biconvex trade dress was "highly persuasive evidence" of secondary meaning).

<sup>23</sup>See *id.* at \*8. (stating that the distribution of 1.1 million starter kits was a factor increasing the likelihood of finding of secondary meaning); *American Home Products v. Chelsea*, 572 F. Supp. at 281, 285 (noting that secondary meaning will likely be established at trial "especially" because of the distribution of millions of starter kits).

<sup>24</sup>See *McNeil-PPC*, 919 F. Supp. at 202.

<sup>25</sup>*CIBA-GEIGY v. Bolar Pharm. Co.*, 747 F.2d 844, 856-857 (3<sup>rd</sup> Cir. 1984).

<sup>26</sup>*SK&F, Co. v. Premo Pharm. Labs., Inc.*, 625 F.2d 1055, 1064 (3<sup>rd</sup> Cir. 1980).

single source.<sup>27</sup> However, the majority-affirmed district court decision found the existence of a similar-looking, different drug to be irrelevant because the two contained different ingredients and each bore a name brand – thus lessening the likelihood of illegal substitution by a pharmacist.<sup>28</sup>

The district court in *CIBA-GEIGY* also noted that a competitor’s copying of the original trade dress sufficed to demonstrate secondary meaning.<sup>29</sup> The district court reasoned that a product’s appearance would not be copied if it had no value, and it is this value that translates into secondary meaning.<sup>30</sup> However, copying has not always been viewed as probative of secondary meaning. In *Par Pharmaceutical v. Searle Pharmaceuticals*, the court stated that copying alone may be insufficient to show secondary meaning, albeit constituting strong evidence thereof.<sup>31</sup> Moreover, in *Marion Laboratories v. Michigan Pharmacal Corp.*, the court rejected the claim that secondary meaning of the plaintiff’s trade dress had been achieved despite the court’s acknowledgement that several companies – including the defendant company – copied the plaintiff’s capsule’s brown and clear appearance as well as other aspects of the drug itself.<sup>32</sup> The court deemed the secondary meaning survey insufficient because the survey was taken after the defendant’s competing brown and white capsule had entered the market.<sup>33</sup> Evidence of promotional strategies and expenses were similarly dismissed due to a lack of “direct evidence” showing that this marketing took place prior to the defendant’s

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<sup>27</sup> *CIBA-GEIGY*, 747 F.2d at 858 n.3.

<sup>28</sup> *Id.* at 851-852, 858 n.3.

<sup>29</sup> *CIBA-GEIGY*, 547 F.Supp. at 1113.

<sup>30</sup> *Id.*

<sup>31</sup> *Par Pharm.*, 1985 U.S. Dist. LEXIS 1664, at \*9-10 (N.D. Ill. 1985); *see also McNeil-PPC*, 919 F. Supp. at 202 (holding that copying alone leads only to a presumption of secondary meaning, but evidence of copying plus a survey of secondary meaning would likely succeed to show secondary meaning in a trial on the merits).

<sup>32</sup> *Marion Labs., Inc. v. Michigan Pharmacal Corp.*, 338 F. Supp. 762, 769 (E.D. Mich. 1972) (granting defendant-look-alike manufacturer’s motion to dismiss because secondary meaning was not established and there was insufficient evidence of palming off).

<sup>33</sup> *Id.*

entrance.<sup>34</sup>

## B. Functionality

Even if a product’s distinctive appearance has acquired secondary meaning, an item will not enjoy trade dress protection if the item’s distinguishing features serve a functional purpose. The standard for functionality entails being “essential to the use or purpose of the article” or “affect[ing] the cost or quality of the article.”<sup>35</sup> Generally, courts have accepted the notion that a drug’s distinctive trade dress is arbitrary and non-functional. However, the Supreme Court has never actually adopted this rationale. Overall, despite the Supreme Court’s lack of clear guidance on the issue, branded pharmaceuticals are likely to prevail over assertions of therapeutic functionality.

Certain trade dress attributes have nevertheless been denied protection because of their functionality. In *SK&F Laboratories v. Clark & Clark*, the Third Circuit held that each aspect of the tablet in question’s trade dress served a function other than source identification: the beveled edges prevented crumbling, the concave bottom facilitated breaking the tablet into smaller doses, the scoring also facilitated breaking the tablet, the round shape was less costly to manufacture and the whiteness was the tablet’s natural color – thus functional.<sup>36</sup> The therapeutic functions of a drug’s appearance have historically gained court acceptance. In 1924, the US Supreme Court deemed the combination of liquid quinine and chocolate functional because the flavoring “supplies the mixture with a quality of palatability for which there is no equally sat-

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<sup>34</sup>*Id.*

<sup>35</sup>*Inwood Labs.*, 456 U.S. at 850 n.10.

<sup>36</sup>*Smith Kline & French Labs. v. Clarke & Clarke*, 157 F.2d. 725, 730 (3<sup>rd</sup> Cir. 1946).

isfactory substitute.”<sup>37</sup>Moreover, in 1959, the Second Circuit found the pink color of Pepto-Bismol to be functional.<sup>38</sup>The court focused on the fact that the pink color was intended to “present a pleasing appearance,” reaching the odd conclusion that “a finding of functional value might well be made because a rejected stomach medicine scarcely has a fair opportunity to fulfill its function.”<sup>39</sup>A district court also ruled, without explanation, that the amber color of mouthwash was functional.<sup>40</sup> However, not every court has accepted the argument that pharmaceutical trade dress serves a therapeutic or practical function. As early as 1953, the Ninth Circuit decided not to consider whether the “valentine-like” shape of a tablet served a function in preventing dropped pills from rolling away.<sup>41</sup>The court instead rejected a functionality claim simply because the purpose of using this particular shape and color was to identify the brand name product.<sup>42</sup>In *Biocraft Laboratories v. Merck & Co.*, the generic manufacturer urged the court to accept the therapeutic value of pharmaceutical trade dress in the context of psychotropic drugs.<sup>43</sup>The court rejected this claim on several grounds.<sup>44</sup>As a general matter, the court deferred to the FDA in determining whether certain drugs are most effective in particular colors.<sup>45</sup>The court also noted that there is no support in current law or custom for the notion that each medication should be distributed with only one type of trade dress

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<sup>37</sup>William R. Warner & Co. v. Eli Lilly & Co., 265 U.S. 526, 529 (1924).

<sup>38</sup>Norwich Pharmacal Co. v. Sterling Drug, Inc., 271 F.2d 569, 572 (2<sup>nd</sup> Cir. 1959).

<sup>39</sup>*Id.*; It should be noted, however, that the driving force behind the *Norwich* decision was the belief that color alone should not be protected – a decision which has since been overruled by the Supreme Court in *Qualitex*, 514 U.S. 159 (1995). See *infra* Part III.

<sup>40</sup>Warner Lambert Co. v. McCrory’s Corp., 718 F. Supp. 389 (D.N.J. 1989). Note that the only discussion following the finding of functionality focused on the fact that colors are not protectable.

<sup>41</sup>*Ross-Whitney*, 201 F.2d at 196.

<sup>42</sup>*Id.* at 197.

<sup>43</sup>*Biocraft Labs., Inc., v. Merck & Co., Inc.*, 532 F. Supp. 1068, 1075-1076 (D.N.J. 1980).

<sup>44</sup>*Id.* at 1075-1077.

<sup>45</sup>*Id.* at 1076.

(regardless of the manufacturer).<sup>46</sup> Focusing on the specific drugs and colors at issue, the court questioned the validity and feasibility of the arguments presented: one of the studies relied on at trial, despite having statistically insignificant results, showed that anxiety patients preferred green tablets, with yellow ranking the least preferable, while those suffering from depression preferred yellow.<sup>47</sup> Since the medication in question is indicated for depression accompanied by anxiety, this finding was deemed confusing and ultimately disregarded.<sup>48</sup> Courts have also rejected the claim that using different colors for different dosages renders a drug's trade dress functional. In *Biocraft Laboratories*, the manufacturer of a brand look-alike asserted that the each color served to identify a particular dosage, and thus lacked protectable status.<sup>49</sup> However, the court responded that:

while color code systems per se are doubtless in the public domain in the sense that a manufacturer using a color code cannot prevent another manufacturer from using a different color code, the uniqueness of each color code for a given manufacturer and product reflects identity and source, which may not be copied.<sup>50</sup>

As there is no set industry standard, the court ruled that the particular selection of colors was arbitrary and non-functional.

Generic manufacturers have also unsuccessfully argued that pharmaceutical trade dress generally serves a function identifying a type of medication – rather than a brand – and that standardization of such trade dress is socially desirable. In *CIBA-GEIGY*, the district court's rejection of the argument that doctors and pharmacists would prescribe medication simply based on its appearance was upheld on appeal.<sup>51</sup> The notion

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<sup>46</sup>*Id.* at 1076.

<sup>47</sup>*Id.* at 1076.

<sup>48</sup>The court further deflates the argument of colors' therapeutic values by noting that one such spectrum is now on display at the National Museum of Quackery maintained by the St. Louis (Missouri) Medical Society. *Id.* at 1076 (citing N.Y. TIMES, Aug. 17, 1980, p. 36).

<sup>49</sup>*Biocraft Labs.*, 532 F. Supp. at 1070.

<sup>51</sup>*CIBA-GEIGY*, 747 F.2d at 851.

that patients would be unable to adjust to new colors for the same medication has also been rejected, with the court ruling that, without evidence to the contrary, the court is “unwilling to believe it to be beyond the ability of patients to stop associating orange with their heart medicine and start thinking of green as the color of the pill taken for their heart condition.”<sup>52</sup> The claim that generic look-alikes avoid patient anxiety caused by switching from brand to generic medication has been similarly rejected. In *SK&F v. Premo*, the Third Circuit refused to accept this argument, noting that most states require consumer notification of any substitution of generic for name brand medication.<sup>53</sup> If a patient is informed about a substitution, the fact that the new, substituted medication looks different is not expected to affect the patient’s level of anxiety.<sup>54</sup> Similar reasoning can be found in *Boehringer Ingelheim v. Pharmadyne*.<sup>55</sup>

Critics of pharmaceutical trade dress protection have also suggested that

standardization can facilitate emergency room identification of drugs in the event of overdose, yet courts have rejected this claim of functionality as well. In *Boehringer Ingelheim*, the court dismissed this contention both because the medication at issue was unlikely to cause an emergency room overdose problem and because the color was unlikely to aid in identifying the active ingredient even if overdose did occur.<sup>56</sup> In *Hoffman-La Roche v. Premo Pharmaceutical Laboratories*, the court rejected the same argument of trade dress functionality in emergency rooms, simply deeming it “unpersuasive.”<sup>57</sup> In *SK&F v. Premo*, this same contention was

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<sup>52</sup> *Boehringer Ingelheim*, 532 F. Supp. at 1049.

<sup>53</sup> *SK&F v. Premo*, 625 F.2d at 1061; see also *Hoffman-La Roche Inc. v. Premo Pharm. Labs., Inc.*, 1980 U.S. Dist. LEXIS 16851, at \*39 (D.N.J. 1980).

<sup>54</sup> *Id.*

<sup>55</sup> *Boehringer Ingelheim*, 532 F. Supp. at 1047-1049.

<sup>56</sup> *Id.* at 1049.

<sup>57</sup> *Hoffman-La Roche*, 1980 U.S. Dist. LEXIS 16851, at \*39.

dismissed because the generic version in question was not bioequivalent.<sup>58</sup>As a result, if the medications have the same appearance, an emergency room technician would have great difficulty ascertaining which type of the drug has been ingested and would not at all be aided by color standardization.

Despite the plethora of cases rejecting the public policy arguments for finding functionality, the US Supreme Court has not yet adopted the same reasoning. In *Inwood v. Ives*, the court appears sympathetic to the district court's view that the blue and blue-red capsules in question served several functions:

many elderly patients associate color with therapeutic effect; some patients commingle medications in a container and rely on color to differentiate one from another; colors are of some, if limited, help in identifying drugs in emergency situations; and use of the same color for brand name drugs and their generic equivalents helps avoid confusion on the part of those responsible for dispensing drugs.<sup>59</sup>

The Supreme Court struck down the Second Circuit's reversal of the district court decision, preserving this approach to functionality. However, the court actually decided on a technicality - that the Second Circuit had overstepped its bounds by reversing without establishing that the lower court's ruling was "clearly erroneous."<sup>60</sup>The Supreme Court did not contribute additional commentary on the subject of functionality, allowing the lowest court's holding to remain unmodified. The Second Circuit followed suit by affirming without an opinion on remand.<sup>61</sup>Several years later, in a decision unrelated to pharmaceuticals, the Supreme Court used a colored capsule's function of identifying a particular type of medication as a prime example of functionality potentially barring trademark protection.<sup>62</sup>Nevertheless, the numerous decisions rejecting similar assertions of functionality were not reversed, and manufacturers seeking protection should still be

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<sup>58</sup>*SK&F v. Premo*, 625 F.2d at 1061

<sup>60</sup>*Id.*

<sup>61</sup>*Ives Labs., Inc. v. Darby Drug Co.*, 697 F.2d 291 (2<sup>nd</sup> Cir. 1982).

<sup>62</sup>*Qualitex*, 514 U.S. at 169 (citing *Ives*, 456 U.S. at 853, 858 n.20).

able to prevail.

## C. Likelihood of Confusion

Beyond the need to determine that the particular trade dress at issue has acquired

secondary meaning and is non-functional, a successful claim of unfair competition requires a proper showing that there is a likelihood of confusion between the original and the look-alike product. Although courts generally are willing to find that a likelihood of confusion exists if the generic and brand drugs have nearly identical appearances at the point of purchase, the courts' findings have varied for confusion of look-alike drugs in different packaging.

The appearance of the generic must be close to identical to that of the brand version to satisfy the likelihood of confusion requirement. In *American Home Products v. Barr*, the court found no likelihood of confusion between Advil and an ibuprofen generic because of differences in shape, sheen, brand imprint, and overall appearance despite the two tablets' similar 'brown' color.<sup>63</sup> The facts in this case were "expressly distinguished" from those in *CIBA-GEIGY* and *SK&F v. Premo*, where the only difference in appearance was the name printed on the drugs.<sup>64</sup> In this case, examination of the tablets alone was not expected to cause consumer confusion.<sup>65</sup> Similarly, in *Florida Breckenridge v. Solway Pharmaceuticals*, the court found the two versions of estrogen-androgen supplement to have only a "low level of similarity": whereas the brand name capsule is described as one-half of an inch long, smooth, glossy, rounded and green, with dark/light

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<sup>63</sup> *American Home Products v. Barr*, 656 F. Supp. at 1063-1064, 1070.

<sup>64</sup> *Id.* at 1071.

<sup>65</sup> *Id.* at 1071.



for different dosages, the generic is five-eighths of an inch long, rough, dull, squared and green, with shade varying similarly per dosage.<sup>66</sup> Finding this to be a noticeable difference and ensuing confusion to be unlikely, the court denied a motion for a preliminary injunction against the generic manufacturer and later granted a motion for summary judgment in favor of the alleged look-alike.<sup>67</sup>

If the only distinguishing factor between the brand name and generic pharmaceutical is the manufacturer's label on the bottle or the manufacturer's name stamped on the particular pills, courts have discounted the differences. The Ninth Circuit has held that different labels on bottles containing otherwise identical medications did not sufficiently minimize the likelihood of confusion.<sup>68</sup> With respect to the name imprinted on the medication itself, the Third Circuit upheld a district court decision that this minor difference did not mitigate the confusingly similar appearances of the capsules in question.<sup>69</sup> The court focused on the "overall physical appearance" and noted that as most of the drug's consumers were over sixty years old, they would be unlikely to see clearly enough to distinguish the two products by name.<sup>70</sup> In *McNeil*, the different imprints on the parties' capsules did not sufficiently differentiate the two because the writing on the generic drug was difficult to see – regardless of the patients' ages.<sup>71</sup> The court bolstered this holding, noting that "the fact that the Tylenol product says 'Tylenol' does not mean that one preparing to ingest the [generic] capsule would know it is not Tylenol."<sup>72</sup> Finally, the court considered "confusion surveys" and found that "'net' confusion

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<sup>66</sup> *Florida Breckenridge*, 1997 U.S. Dist. LEXIS 17574, at \*18-19.

<sup>67</sup> *Id.* at \*30; *Florida Breckenridge, Inc. v. Solvay Pharm., Inc.*, U.S. Dist. LEXIS 14742, at \*17-18 (S.D. Fla. 1998).

<sup>68</sup> *Ross-Whitney Corp.*, 207 F.2d at 196-197.

<sup>69</sup> *CIBA-GEIGY*, 747 F.2d at 851 (citing *CIBA-GEIGY*, 547 F. Supp. at 1103).

<sup>70</sup> *Id.*

<sup>71</sup> *McNeil*, 919 F. Supp. at 202.

<sup>72</sup> *Id.*

level[s]” of twenty-eight and twenty-one percent satisfied the showing for a likelihood of confusion.<sup>73</sup>

Courts have, however, produced inconsistent rulings on the proper time – point of purchase versus point of consumption – for considering the likelihood of confusion.<sup>74</sup> Where courts have been sympathetic to point of purchase advocates, brand name manufacturers often lose. In *Norwich*, the Second Circuit used the point of purchase as the reference point and subsequently found no possibility for confusion between the brand name and generic version.<sup>75</sup> Even though the generic pink liquid medication was “virtually identical to Pepto-Bismol,” the court found the differences in bottle shapes, bottle cap appearances, and colors on the labels to be so great that “it stretches the credulity to imagine a purchaser confusing these disparate articles.”<sup>76</sup> Moreover, *Smithkline Beckman v. Pennex Products* held that the analysis of likelihood of confusion should focus on the purchase point, reasoning that a buyer cannot be confused if the product as a whole he or she is purchasing looks, at this time of purchase, completely different from that of the name brand.<sup>77</sup> Consequently, the court found that a likelihood of confusion existed where one defendant-generic manufacturer sold tablets identical to the brand name originals in translucent bottle, but rejected this claim against another defendant whose tablets came in a non-translucent bottle, packaged in a box.<sup>78</sup> In contrast,

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<sup>73</sup>*Id.* The court also looked to other circuit courts that took into account confusion surveys with even lower levels of confusion. *McNeil*, 919 F. Supp. at 202-203 (citing *Mutual of Omaha Ins. Co. v. Novak*, 836 F.2d 397, 400 (8th Cir. 1987) (finding that a survey showing a confusion level of approximately 10% should be given substantial weight); *Exxon Corp. v. Texas Motor Exchange*, 628 F.2d 500, 507 (5<sup>th</sup> Cir. 1980) (noting that survey results of 15-23% confusion levels are strong evidence in favor of a finding of a likelihood of confusion). Moreover, other circuit courts have ruled similarly. See, e.g., *James Burrough, Ltd. v. Sign of Beefeater, Inc.*, 540 F.2d 266 (7<sup>th</sup> Cir. 1976) (finding a 15% level to be evidence of confusion).

<sup>74</sup>The debate over timing with respect to purchasing the pharmaceutical pertains only to cases of over-the-counter, “OTC,” drugs since pharmacists rather than consumers have sole access to the original product packages for prescription medication. See, e.g., *Smithkline Beckman Corp. v. Pennex Products Co.*, 605 F. Supp. 746, 752 (E.D. Pa. 1985) (noting that prescription drugs are a “unique commodity” which “cannot be compared side by side with another product. This is contrasted with shelf medication which can be compared . . . and comes in many unique packaging configurations which help indicate the source of the product”).

<sup>75</sup>*Norwich*, 271 F.2d at 571-572.

<sup>76</sup>*Id.* at 570, 571.

<sup>77</sup>*Smithkline Beckman*, 605 F. Supp. at 751.

<sup>78</sup>*Id.* at 751-752.

other courts consider assertions of confusion from the post-purchase vantage point. *American Home Products v. Chelsea* confirmed the viability of actions based on post-purchase confusion.<sup>79</sup> The court distinguished its findings from *Smithkline Beckman* by pointing out that the plaintiffs in the case at bar blame all confusion on the similarity in color while the plaintiffs in *Smithkline Beckman* primarily attributed confusion to the wide-spread misconception that name brand manufacturers produced their own generic versions, as well.<sup>80</sup> However, the court also advanced a more powerful argument for refusing to follow the holding in *Smithkline Beckman*:

I can see no reason in law or fact why, in an age of skilled and subtle techniques for marketing consumer products and winning new customers, courts should refuse to take cognizance of unfair competitive practices which work themselves out over two, three or more experiences with a product, rather than quickly, at the moment a consumer first sees two opposing products on a shelf and reaches for only one of them.<sup>81</sup>

Consequently, the court rejected the argument that product packaging should be factored into trade dress considerations, noting that some consumers were likely to see the tablets without packaging and, at this point, the difference in packaging would have no effect on the likelihood of confusion between the brand name and generic alternative.<sup>82</sup> The potential for post-purchase confusion was also acknowledged in *McNeil*, where the court focused on the similarity of the red and yellow Tylenol and generic capsules and did not mention the packaging for the drugs in question.<sup>83</sup> The court's conclusion was also based on brand's assertion that post-purchase confusion can occur in the realm of OTC analgesics and the court's acceptance of the brand's confusion surveys.<sup>84</sup>

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<sup>79</sup> *American Home Products v. Chelsea*, 656 F. Supp. at 1069.

<sup>80</sup> *Id.* at 1069.

<sup>82</sup> *Id.* at 1071.

<sup>83</sup> *McNeil*, 919 F. Supp. at 203.

<sup>84</sup> *Id.*

#### D. Vicarious Liability

*The Lanham Act §43(a) also proscribes unfair competition through passing off. Generic manufacturers cannot ‘pass off’ their products as those of the brand name directly, nor can they encourage pharmacists to ‘pass off’ generics as name brand drugs to unknowing consumers. As pharmacists are more knowledgeable than average consumers and more aware of the medications’ sources, the deception usually occurs in the latter situation. Dating back to 1924, the Supreme Court stated that even though the manufacturer did not dupe the retailers, the “wrong was in designedly enabling the dealers” to deceive the customers.*<sup>85</sup> While the Supreme Court has adopted a more stringent standard for finding vicarious liability than the relatively low standard of proof used by many lower courts, this avenue of protection remains available to brand manufacturers seeking trade dress protection.

Findings of passing off have often been based on evidence of substitutions unauthorized by the consumer, along with inferences that agents of the generic manufacturer encouraged the pharmacist to take such action. In *William R. Warner & Co.*, the Supreme Court based its finding of passing off both on actual instances of passing off to consumers as well as its belief - despite conflicting testimony - that agents selling the generic product induced substitution either directly or simply by suggestion.<sup>86</sup> However, evidence of actual substitution is not necessary to prove palming off. Ruling that passing off had occurred, the court in *SK&F v. Clark & Clark* focused on the “feasibility of substitution,” which, the court believed, was suggested to the pharmacists by salesmen working for the generic manufacturer.<sup>87</sup> That the manufacturer was responsible for planting this idea was inferred from evidence showing that the sales representatives emphasized the similar

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<sup>85</sup> *William R. Warner & Co.*, 265 U.S. at 530.

<sup>86</sup> *Id.*

<sup>87</sup> *SK&F v. Clarke & Clarke*, 157 F.2d at 731.

identities of the drugs and the potential for increased profit should the generic be sold in place of the brand name product.<sup>88</sup>*SK&F v. Heart* found that there was no explanation for imitating the brand name product's design other than to induce fraudulent substitution by pharmacists.<sup>89</sup>The court thus held that advertisements to pharmacists showing the drug's shape, describing the drug's color, and touting the low price of the generic constituted sufficient evidence of inducement.<sup>90</sup> Some courts have gone even further, holding manufacturers of generics with identical trade dress to be almost automatically responsible for any substitution that occurs. *Hoffman-La Roche* held the generic manufacturer liable for passing off as a direct result of copying the brand name appearance without addressing allegations of misconduct by defendant's sales agents.<sup>91</sup> According to the court, by producing look-alike generics, the manufacturer "has tossed the lighted squib, it has deliberately provided the means for deception" and "[i]t would be obliged, if it wished to compete, to do so by employing a distinctive trade dress of its own, as different as possible from Roche's."<sup>92</sup> Intent to encourage substitution was also inferred in *Pennwalt* where the generic manufacturer's adoption of brand name product design was deemed the "supporting keystone which transforms these circumstances into an edifice for deception," and evidence of actual illegal substitutions merely bolstered this foregone conclusion.<sup>93</sup> Consequently, copying the trade dress can result in a type of strict liability standard for passing off claims.

*Marion Laboratories* rejected the claim of passing off, however, despite the generic drug's identical appearance

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<sup>88</sup> *Id.*

<sup>89</sup> *SK&F v. Heart*, 90 F. Supp. 976, 978 (S.D.N.Y. 1950).

<sup>90</sup> *Id.*; see also *Boehringer Ingelheim*, 532 F. Supp. at 1052 (noting that "[b]y drawing attention to the comparability of the product and the identity of colors, defendants have made drug wholesalers and pharmacist buyers of generic dipyridamole aware that the customer can be surreptitiously given their less expensive generic product in the place of the more costly [brand name] Persantine"); *A.H. Robbins Co. v. Med. Chest Corp.*, 1980 U.S. Dist. LEXIS 14412, at \*12 (E.D. Mo. 1980) (listing factors including intentionally copying appearance, drawing attention to the mimicked color of the generic, and emphasizing the difference in price in finding that the look-alike manufacturer knew or should have known that the generics were illegally substituted for the brand drug).

<sup>91</sup> *Hoffman-La Roche*, 1980 U.S. Dist. LEXIS 16851, at \*31-37.

<sup>92</sup> *Id.* at \*37.

<sup>93</sup> *Pennwalt*, 472 F. Supp. at 420 (analyzing the facts with respect to state unfair competition claims).

to the brand name product.<sup>94</sup>With no proof of actual substitutions or salesman misconduct and with generic promotional materials that referred only to the brand name and not the appearance of the generic in question, evidence of passing off was found to be lacking.<sup>95</sup> Look-alike manufacturers may also be held liable for contributory infringement, where pharmacists illegally substitute the generic pharmaceutical for the name brand.<sup>96</sup>However, this claim has been advanced only in *Inwood Laboratories* where it was unsuccessful.<sup>97</sup>In this case, evidence that probably would have been sufficient to prove passing off was deemed not enough to implicate the generic manufacturer for contributory infringement.<sup>98</sup>The Supreme Court reinstated the district court's findings that pharmacist catalogs containing comparisons of price and information on the look-alike's appearance "could not 'be fairly read' to encourage infringement."<sup>99</sup>In his concurrence, Justice White singled out pharmaceuticals as a field where stringent requirements for contributory infringement are especially important so that customers can take look-alike generic drugs.<sup>100</sup> Although it is possible that *Inwood's* holding could affect the standard for §43 passing off claims, no court has applied *Inwood* in this fashion. The Third Circuit in *CIBA-GEIGY* declined to answer this question.<sup>101</sup>Instead, the court simply distinguished the facts from those in *Inwood*, emphasizing that the trial court in the case at bar found that at least one of the motivations for copying the brand's trade dress was to induce illegal substitution.<sup>102</sup>The

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<sup>94</sup>*Marion Labs.*, 338 F. Supp. at 769-770. The court also rejected assertions that color of the brand name pharmaceutical had acquired secondary meaning, and thus the plaintiff lost on both theories of unfair competition. *Id.* at 768-769.

<sup>95</sup>*Id.*

<sup>96</sup>15 USC § 1114 (2002).

<sup>97</sup>*Inwood Labs.*, 456 U.S. at 851-853.

<sup>98</sup>*Id.*; Cf. *SK&F v. Heart*, 90 F. Supp. at 978; *Boehringer Ingelheim*, 532 F. Supp. at 1052; *A.H. Robbins*, 1980 U.S. Dist. LEXIS 14412, at \*12.

<sup>99</sup>*Inwood Labs.*, 456 U.S. at 852 (citing *Ives Labs.*, 488 F. Supp. at 397).

<sup>100</sup>*Id.* at 861; *But see supra* notes 121 – 124 and accompanying text.

<sup>101</sup>*CIBA-GEIGY*, 747 F.2d at 854.

<sup>102</sup>*Id.*

Supreme Court declined to hear *CIBA-GEIGY*,<sup>103</sup> and thus, at the moment, courts are not bound to this more stringent standard for passing off.<sup>104</sup>

## E. Equitable Relief

A brand name manufacturer must overcome a few additional hurdles to win an injunction preventing generic drugs from being distributed with the same product design. The original distributor can seek a preliminary injunction before trial and a permanent injunction at trial to prevent the opposing party from selling generic versions in the same color, shape, texture or any other distinctive feature as the brand name medication:

The several courts vested with jurisdiction of civil actions arising under this Act shall have power to grant injunctions, according to the principles of equity and upon such terms as the court may deem reasonable, to prevent the violation of any right of the registrant of a mark registered in the Patent and Trademark Office or to prevent a violation under subsection (a), (c), or (d) of section 43 [15 USCS § 1125].<sup>105</sup>

For preliminary injunctions, courts have interpreted this mandate to require a showing beyond a likelihood of success on the merits that the movant would be irreparably harmed without an injunction, that the balance of equities weighs in favor of the movant, and that the public would be best served by such an injunction.

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<sup>103</sup>*Bolar Pharm. Co., Inc. v. CIBA-GEIGY Corp.*, 471 U.S. 1137 (1985).

<sup>104</sup>It should be noted, however, that an article in the National Law Journal criticized the CIBA-GEIGY ruling and advocated for the adoption of the more stringent standard: “First, if ‘reasonable anticipation’ continues to be a viable standard under Sec. 43(a), then the Supreme Court’s decision in *Ives* [Inwood] is meaningless; future litigants simply will rely on Sec. 43(a) and obtain relief under a legal standard that the Supreme Court questioned in *Ives*. Second, it is apparent that the ‘reasonable anticipation’ standard virtually guarantees a violation of Sec. 43(a) whenever there has been copying since one can always ‘reasonably’ anticipate that some unscrupulous merchants will attempt to enhance their profits by passing off a less expensive generic product for costlier goods.” Kenneth A. Plevan & Miriam L. Siroky, *The 3d Circuit Gets a Dose of Suits Filed against ‘Look-Alike’ Drugs*, NAT’L L. J., Aug. 12, 1985, at 22.

## 1. Irreparable Harm

Courts have accepted claims of irreparable harm based on financial loss, vulnerability to product liability suits for which another manufacturer may be at fault, and damage to goodwill. Such findings do not require the party seeking the injunction to show actual evidence of lost sales due to trade dress infringement. Illegal substitutions are unlikely to be discovered as pharmacists are not expected to turn themselves in for committing an illegal action and patients are probably unaware of the switch given the close resemblance of the generic to the brand name medication. This led the district court in *Par Pharmaceuticals* to order an injunction and declare it “impossible” for the movant to calculate the full extent of the fiscal loss on account of such substitutions.<sup>106</sup> The court also noted that condoning the use of generic look-alikes would impose an additional cost on the brand manufacturer of informing interested parties that it is not the sole manufacturer of a particular drug in a particular trade dress.<sup>107</sup>

Courts have also accepted the argument that since generic look-alikes are virtually indistinguishable from name brand drugs, the manufacturer risks being held responsible should a consumer have a bad reaction to a substituted generic.<sup>108</sup> Any bad experience a consumer has with a drug, which he or she believes to be the brand name, but is actually the identical generic, can cause irreparable damage to the brand’s reputation and goodwill.<sup>109</sup> Moreover, if a product liability lawsuit resulted:

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<sup>106</sup> *Par Pharm.*, 1985 U.S. Dist. LEXIS 16648, at \*15.

<sup>107</sup> *Id.*

<sup>108</sup> *SK&F v. Premo*, 625 F. 2d at 1066.

<sup>109</sup> See *McNeil-PPC*, 919 F. Supp. at 204; *Pennwalt*, 472 F. Supp. at 421.



the striking similarity in appearance of the two products would make it unlikely that [the brand manufacturer], the deep pocket defendant, could prove that the harm was caused instead by [generic] capsules, because the only proof as to the source would be the capsules themselves, long since digested by the patient.<sup>110</sup>

The court thus deemed this risk, along with the acknowledgement that lost sales would be difficult to quantify, sufficient to show that the movant could be irreparably harmed if the distribution of generic look-alike capsules continued.<sup>111</sup>

## 2. Balance of Equity

Once a court concludes that a claim of unfair competition has been proven, the balance of equity generally tips in favor of the brand name manufacturer who is allegedly suffering from unfair competition.<sup>112</sup> After rejecting the assertions that the brand drug's trade dress was functional and that copying the trade dress enabled the generic manufacture to compete more effectively, the Third Circuit in *SK&F v. Premo* described a record "almost totally devoid of equities" in favor of the generic manufacturer.<sup>113</sup> Declaring that trade dress appropriation did not have "the look, sound or feel of equity," the court upheld a finding that the balance tipped in favor of the movant.<sup>114</sup> Other courts have considered the generic manufacturer's claims of financial injury should an injunction be granted, but the asserted benefits of the injunction often prevail. *Pennwalt*

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<sup>111</sup>See also *American Home Products v. Chelsea*, 572 F. Supp. at 286; *CIBA-GEIGY*, 547 F. Supp. at 1116, *Hoffman-La Roche*, 1980 U.S. Dist. LEXIS 16851, at \*41; *Boehringer Ingelheim*, 532 F. Supp. at 1065.

<sup>112</sup>In considering a permanent injunction, the U.S. Supreme Court found that the balance of equities weighed against the injunction despite a finding of unfair competition. Holding an injunction to be excessive, the court instead required the generic manufacturer to label its product distinctively and to include a notice on the label that this product is not to be confused with that of the name brand. *William R. Warner & Co.*, 265 U.S. at 532-533.

<sup>113</sup>*SK&F v. Premo*, 625 F.2d at 1066-1067; see also *CIBA-GEIGY*, 547 F. Supp. at 1116; *Par Pharm.*, 1985 U.S. Dist. LEXIS 16648, at \*16; *Hoffman-La Roche*, 1980 U.S. Dist. LEXIS 16851, at \*42; *Boehringer Ingelheim*, 532 F. Supp. at 1065-1066.

<sup>114</sup>*Id.*

described weighing the competing equity interests as an attempt to “balance the interest in free competition against the interest in securing to businesses the fruits of their initiative and enterprise.”<sup>115</sup> That the drugs in question were not bioequivalent bolstered the case against the generic manufacturer as the injunction would prevent illegal substitutions of such generics from going undetected.<sup>116</sup> The court added that the injunction would deter pharmacists from making illegal substitutions, especially since the governing law on substitution was deemed unclear.<sup>117</sup> Moreover, since the generic manufacturer currently offers a version of the same generic in different colors, the threat to ‘free competition’ is tempered as well.<sup>118</sup> An injunction’s harm to the generic manufacturer was also discounted in *McNeil*, where the court noted that the manufacturer deliberately copied the brand’s trade dress and thus any subsequent harm caused by an injunction would be due to its “own making.”<sup>119</sup>

### 3. Public Interest

Several courts have found that trade dress protection serves the over-arching public interest as well. That generic look-alikes may actually differ in efficacy or absorption rates<sup>120</sup> from the original presents a strong public policy argument for enforcing trade dress protection of name brand medication. In *American Home Products v. Chelsea*, the court distinguished prescription medication from all other items as a field where trade dress protection is of utmost importance; when dealing with pharmaceuticals, substitution of look-alike

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<sup>115</sup> *Pennwalt*, 472 F. Supp. at 421.

<sup>116</sup> *Id.*

<sup>117</sup> *Id.*

<sup>118</sup> *Id.*

<sup>119</sup> *McNeil-PPC*, 919 F. Supp. at 204.

<sup>120</sup> See *SK&F v. Premo*, 625 F.2d at 1061; *American Home Products v. Chelsea*, 572 F. Supp. at 281.

generics harms not only the brand manufacturer from a decrease in sales but also the patient from ingesting a drug of potentially less quality or having a different rate of absorption in the body.<sup>121</sup> The court concluded that “[f]rom a public interest point of view, the risk of harm to the patient stands highest on the scale,” thus strengthening the case against generics with the same appearance.<sup>122</sup> Where the generic medication in question was not bioequivalent, the Third Circuit similarly called the public interest in preventing such generics from appearing identical to the brand name version to be a “a highly significant factor favoring pendente lite relief.”<sup>123</sup> In the end, precluding the manufacture of look-alike generics better protects against illicit substitutions of pharmaceuticals, than policing individual pharmacists. An article in the Trademark Reporter noted that, an “old saw advises that we ‘lock our barn doors and keep our neighbors honest’; trademark registration is the best lock available.”<sup>124</sup> Trade dress protection can also be viewed as pro-competitive. Deeming shortsighted the assertion that look-alike generics force brand manufacturers to compete, the Third Circuit posited that in the long run, encouraging companies to maintain brand recognition would benefit society:

The adoption of a distinctive trade dress as a means of identifying a product with its source is a legitimate means for the promotion of the user’s business, and permitting piracy of that identifying trade dress can only discourage other manufacturers from making a similar individual promotional effort. Moreover, allowing a manufacturer to be able to acquire and maintain a reputation for consistent good quality is certainly pro-competitive. Permitting a business climate in which substitution of products over which the first manufacturer has no quality control in the long run can only discourage the effort to compete on the basis of reputation for quality.<sup>125</sup>

As brand manufacturers have no control over the quality of the generic drugs, permitting the existence of virtually indistinguishable generics lessens a brand’s incentives to promote the brand and to maintain high

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<sup>121</sup> *American Home Products v. Chelsea*, 572 F. Supp. at 281.

<sup>122</sup> *Id.*

<sup>123</sup> *SK&F v. Premo*, 625 F.2d at 1067.

<sup>124</sup> Iver P. Cooper, *Trademark Aspects of Pharmaceutical Product Design*, 70 TRADEMARK REP. 1, 46 (Jan. – Feb., 1980).

quality standards. Generic look-alikes can be thus considered detrimental to the community.

### III.

#### Trademark Protection of Color Alone

Along with trade dress protection for pharmaceutical product design as a whole, brand name pharmaceuticals can obtain trademark registrations for individual features of the design, such as color. Trademark infringement falls under the general rubric of unfair competition.<sup>126</sup> The difference between trademark and trade dress is that trade dress involves the overall marketing scheme, whereas a trademark focuses only on a particular symbol of the product's source.<sup>127</sup> Trademark protection offers additional benefits, including the right to bar importation of confusingly similar goods, constructive notice of mark ownership, the opportunity for incontestable status, and prima facie evidence of trademark validity and ownership.<sup>128</sup> Both trademark and trade dress infringement suits require a showing of secondary meaning,<sup>129</sup> non-functionality, and a likelihood of confusion.<sup>130</sup> Although the standards for secondary meaning and functionality are virtually interchangeable,<sup>131</sup> courts have wrestled with the idea of requiring a higher standard for the likelihood of confusion for color trademarks. Historically, courts resisted granting trademark protection for a color

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<sup>126</sup> See *Deere & Co. v. Farmhand, Inc.*, 560 F. Supp. 85, 94 (S.D. Iowa 1982), *aff'd*, 721 F.2d 253 (8<sup>th</sup> Cir. 1983) (referring to McCarthy, Trademarks and Unfair Competition, sec. 2:2 (1973) and reports on the bill that became the Lanham Act S.R. 1333, 79<sup>th</sup> Cong. 2d sess. (1946)).

<sup>127</sup> *Deere*, 560 F. Supp. at 94.

<sup>128</sup> See *Qualitex*, 514 U.S. at 174 (citing 15 U.S.C. §1124, §1072, §1065, §1057(b)).

<sup>129</sup> A showing of secondary meaning is required unless the mark is deemed inherently distinctive. See *infra* Part IV.A.

<sup>130</sup> *Id.* at 95 (citing *Truck Equipment Service Co. v. Fruehauf Corp.*, 536 F.2d 1210 (8<sup>th</sup> Cir. 1976); see also *Vaughan Mfg Co. v. Brikam Int'l, Inc.* 814 F.2d 346, 348 n.2 (7<sup>th</sup> Cir. 1986)).

<sup>131</sup> *Vaughan Mfg. Co.*, 814 F.2d at 348 n.2.

by itself, but the Supreme Court turned the tides in *Qualitex v. Jacobson Products*.<sup>132</sup> This watershed case has not been specifically interpreted in the context of pharmaceuticals, but the ruling nevertheless supports brand manufacturers' right to protect individual aspects of product designs.

## A. The Traditional Rule

Traditionally, color, per se, could not receive trademark protection. Years before the Lanham Act was introduced in 1946, the Supreme Court noted in dicta that “you cannot register a mark of which the only distinction is the use of a color. . . .”<sup>133</sup> As a result, there was a general prohibition on registering colors.<sup>134</sup> After the enactment of the Lanham Act in 1946, the notion that color alone could not be protected from copying remained, even though no such bar was explicitly stated.<sup>135</sup> The Act defined a “trademark” as “any word, name, symbol, or device, or any combination thereof . . .”<sup>136</sup> – which could certainly include a color – and delineated a set of unregistrable items<sup>137</sup> – which did not mention color. However, many courts followed *Leschen* instead of looking to the new legislation.

The post-Lanham Act rejection of color alone trademarks was partly based on resistance to change. In

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<sup>132</sup>*Qualitex*, 514 U.S. at 174 (1995).

<sup>133</sup>*Leschen & Sons Rope Co. v. Broderich & Bascom Rope Co.*, 201 U.S. 166, 172 (1906) (quoting *In re Hanson's Trade-mark*, 37 Ch. D. 112, 116 (1887)).

<sup>134</sup>*See, e.g., In re Gen. Petroleum Corp of California*, 18 C.C.P.A. 1444 (CCPA 1931) (rejecting a trademark application for violet gasoline); *In re Sec. Eng'g Co., Inc.*, 27 C.C.P.A. 1389 (CCPA 1940) (denying protection for blue-and-aluminum oil well reamers).

<sup>135</sup>*See* 15 U.S.C. 1051-1127 (1988 & Supp. V 1993).

<sup>136</sup>15 U.S.C. 1127 (1988 & Supp. V 1993).

<sup>137</sup>15 U.S.C. 1052 (1988 & Supp. V 1993).

*Campbell Soup Co. v. Armour & Co.*, the Third Circuit simply proclaimed “[t]hat a man cannot acquire a trade-mark by color alone has been stated a good many times in decisions and textbooks” without giving any thought to protectability of the colors at issue.<sup>138</sup> Similarly, in denying protection to the pastel blue of “Equal” sugar substitute packets, the Seventh Circuit chose to maintain the status quo in barring color alone protection, noting that “[c]onsistency and predictability of the law are compelling reasons for not lightly setting aside a settled principle of law.”<sup>139</sup> The court declared that there was “no need” to bring about change.<sup>140</sup> Along with an aversion to change, courts advanced theoretical arguments against the protection of color per se. For example, the color depletion theory assumes that the supply of colors for marketable products is limited, and critics of color alone protection assert that if individual brands win exclusive rights to sell products in designated colors, the supply of available colors for competing manufacturers will diminish until no colors are left.<sup>141</sup> Dating back to 1906, the Sixth Circuit expressed this belief, claiming that the only available colors were primary colors as well as black and white.<sup>142</sup> In the debate over protection of the red and white Campbell Soup labels, the Third Circuit worried that if successful, “they may thus monopolize red in all of its shades[,] the next manufacturer may monopolize orange in all its shades and the next yellow in the same way. Obviously, the list of colors will soon run out.”<sup>143</sup> Others have argued that the supply will be further reduced because certain colors are not marketable to consumers:

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<sup>138</sup>*Campbell Soup Co. v. Armour & Co.*, 175 F.2d 795, 798 (3<sup>rd</sup> Cir. 1949) (citing *Leschen*, 201 U.S. 166; *Samson Cordage Works v. Puritan Cordage Mills*, 211 F. 603 (6<sup>th</sup> Cir. 1914); *James Heddon’s Sons v. Millsite Steel & Wire Works*, 128 F.2d 6 (6<sup>th</sup> Cir. 1942); 1 Nims, *Unfair Competition and Trade-Marks* §210b; 2 Callmann, *Unfair Competition and Trade Marks* sec. §71.5 (1945).

<sup>139</sup>*NutraSweet Co. v. Stadt Corp.*, 917 F.2d 1024, 1027 (8<sup>th</sup> Cir. 1990).

<sup>140</sup>*Id.*

<sup>141</sup>See James L. Vana, *Color Trademarks*, 7 TEX. INTELL. PROP. L.J. 387, 388-389 (Spring, 1999); Jean Hayes Kearns, *Comment: Qualitex Co. v. Jacobson Products Co.: Orange You Sorry the Supreme Court Protected Color?*, 70 ST. JOHN’S L. REV. 337, 353-357 (Spring, 1996).

<sup>142</sup>*Diamond Match Co. v. Saginaw Match Co.*, 142 F. 727, 729 (6<sup>th</sup> Cir. 1906); see also *Pacific Coast Condensed Milk Co. v. Frye & Co.*, 85 Wash. 133, 147 (1915) (noting that “the primary colors are few. . .”).

<sup>143</sup>*Campbell Soup*, 175 F. 2d at 798.

By the time one discards colors that, say, for reasons of customer appeal, are not usable, and adds the shades that competitors cannot use lest they risk infringing a similar registered shade, then one is left with only a handful of possible colors.<sup>144</sup>

Accordingly, if the supply is so limited, and if every market player acts to secure an identifiable color for its product, entrants to the market will face increasing difficulty in competing effectively.<sup>145</sup> Seeking protection for its blue sugar substitute packets, NutraSweet pushed for the adoption of a case-by-case analysis, where the court would allow protection only after determining that there was no “competitive need” for the color to remain available to competitors.<sup>146</sup> However, the court dismissed this suggestion as “unworkable” and maintained it could not foresee the needs of future competitors.<sup>147</sup>

Critics of color per se protection also point to the difficulties of shade confusion to support their position. Shade confusion is premised on the notion that courts and the Trademark Trial & Appeal Board (T.T.A.B.)<sup>148</sup> do not have the expertise to compare colors and determine the likelihood of consumer confusion.<sup>149</sup> Courts have thus refused to grant protection in part because of their “desire that infringement actions not denigrate into questions of shade confusion.”<sup>150</sup> The comparison of colors is ostensibly more complex than the comparison of the sounds of words and phrases because a color’s appearance can be altered by the light under which it is

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<sup>145</sup>*Id.* The registration of a color will not necessarily prevent another manufacturer from using this color for a different product, as long as there is not close “proximity of the products.” Karin S. Schwartz, *It Had to be Hue: The Meaning of Color “Pure and Simple,”* 6 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 59, 76-77 (Fall, 1995) (citing the standard established in *Polaroid Corp. v. Polorad Elecs., Corp.*, 287 F.2d 492, 495 (2<sup>nd</sup> Cir. 1961), *cert denied*, 368 U.S. 820 (1961)).

<sup>146</sup>*NutraSweet*, 917 F.2d at 1027.

<sup>147</sup>*Id.*

<sup>148</sup>The T.T.A.B. reviews contested trademark registrations.

<sup>149</sup>See Vana, *supra* note 141, at 389; Kearns, *supra* note 141, at 346-353.

<sup>150</sup>*W.H. Brady Co. v. Lem Prods., Inc.*, 659 F. Supp. 1355 (N.D. Ill. 1987); see also *In re Owens-Corning Fiberglas Corp.*, 774 F.2d 1116, 1131 (Fed. Cir. 1985) (dissent echoing the same shade confusion argument); *NutraSweet*, 917 F.2d at 1027 (declining to assume responsibility for determining just how different colors must be to avoid a likelihood of confusion).

viewed.<sup>151</sup>Moreover, the juxtaposition of two colors can arguably change a color's appearance.<sup>152</sup>Finally, shade confusion devotees have maintained that since color perception is subjective, competitors will have to avoid the entire range of shades of a protected color to prevent litigation.<sup>153</sup>

## B. Challenge of the Traditional Rule

In 1985, the Federal Circuit decided *Owens-Corning Fiberglas Corp.* and was the first circuit court to recognize trademark protection for a color.<sup>154</sup>This appeal arose out of a T.T.A.B. ruling that while an overall color could receive trademark protection, the color “pink” for fibrous glass residential insulation was denied registration due to an insufficient showing of the color's distinctiveness.<sup>155</sup>The Federal Circuit confirmed the lower court's ruling that color alone was worthy of protection and reversed the T.T.A.B., finding the evidence of a public association of the mark with the manufacturer to be more than sufficient.<sup>156</sup> Most importantly, *Owens-Corning* categorically rejected all of the arguments used by opponents of trademark protection for colors. As a general matter, the court likened over-all color to over-all surface design, which was eligible for

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<sup>151</sup>Kearns, *supra* note 141, at 349-350; *see also Qualitex*, 514 U.S. at 167 (referencing respondent's assertion that lighting such as “morning sun, twilight mist” can change perceptions of color).

<sup>152</sup>Kearns, *supra* note 141, at 349-350 (citing evidence that a green item on a red shelf appears different from a green item on a grey shelf).

<sup>153</sup>*Id.* at 350-352.

<sup>154</sup>*See Owens-Corning Fiberglas Corp.*, 774 F.2d at 1118.

<sup>155</sup>*In re Owens-Corning Fiberglas Corp.*, 221 U.S.P.Q. (BNA) 1195, 1199 (T.T.A.B. 1984).

<sup>156</sup>*Owens-Corning Fiberglas Corp.*, 774 F.2d at 118-1123, 1127.



protection.<sup>157</sup> The court also rejected all of the theoretical arguments against registering color alone. The color depletion theory was referred to as an “unreasonable restriction on the acquisition of trademark rights,” since the practice of dyeing such fiberglass was uncommon and unlikely to hinder competition in the industry.<sup>158</sup> The court also followed the lower court’s rejection of the shade confusion argument, noting that the requisite likelihood of confusion analysis between shades would be no more taxing on the judiciary than the current likelihood of confusion among different words.<sup>159</sup> Consequently, since the color pink served no function other than identifying the brand of the insulation, it was deemed deserving of trademark protection.<sup>160</sup> The Eighth Circuit soon followed suit in *Master Distributors, Inc. v. Pako Corp.*, declining to adopt an absolute prohibition against color alone protection.<sup>161</sup> The court adopted the Federal Circuit’s interpretation of the Lanham Act, noting that the bounds of trademark protection did not exclude color marks.<sup>162</sup> Unlike color protection opponents who felt that preventing protection and honoring precedent were crucial to the stability of the system, the court posited that barring such protection would actually lead to “confusion and inconsistency.”<sup>163</sup> The Eighth Circuit rejected the color depletion argument pointing out that the spectrum of available colors is indeed much larger than the limited palette of primary colors; a color atlas listed 1,266 colors and the National Bureau of Standards acknowledged 267 hues.<sup>164</sup> Masters Distributors also

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<sup>157</sup>*Id.* at 1122-1123 (citing *In re Todd Co.*, 290 F.2d 597, 600 (CCPA 1961) (accepting the registration of a pattern of green parallel lines for safety paper products); *Vuitton et Fils S.A. v. J. Young Enterprises, Inc.*, 644 F.2d 769, 775 (9<sup>th</sup> Cir. 1981) (allowing an overall pattern of florets and letters to receive trademark protection).

<sup>158</sup>*Id.* at 1122 (citing *Owens-Corning Fiberglas Corp.*, 221 U.S.P.Q. at 1198).

<sup>159</sup>*Id.* at 1123 (citing *Owens-Corning Fiberglas Corp.*, 221 U.S.P.Q. at 1198).

<sup>160</sup>*Id.* at 1123, 1128.

<sup>161</sup>*Master Distributors, Inc. v. Pako Corp.*, 986 F.2d 219, 224 (8<sup>th</sup> Cir. 1993).

<sup>162</sup>*Id.* (citing *Owens-Corning Fiberglas Corp.*, 774 F.2d at 1119).

<sup>163</sup>*Id.*

<sup>164</sup>*Id.* at 223 (referring to A. Kornerup & J.H. Wanscher, *Color Atlas* 7 (1961); Kenneth L. Kelly & Deane B. Judd, *Color: Universal Language and Dictionary of Names* 4 (1976)).

emphasized that color protection extended only to a particular shade of a color, thus no manufacturer would be receiving the right to “monopolize red ‘in all its shades.’”<sup>165</sup> While the court conceded that color protection might require the judiciary to confront shade confusion problems, it maintained that the determination of a likelihood of confusion among colors was no more taxing than that for any other type of mark.<sup>166</sup> Since several courts had already dealt with shade confusion problems and since experts could aid the court in differentiating between colors, the court was unmoved by the argument that color mark infringement cases would be more complex.<sup>167</sup>

### C. The Supreme Court Speaks: Traditional Rule Abolished

The Federal Circuit’s innovative rationale in *Owens-Corning* was rejected by the Seventh Circuit but adopted by the Eighth Circuit,<sup>168</sup> and the Supreme Court soon agreed to resolve the circuit split. In 1995, *Qualitex v. Jacobson Products* ended the color per se controversy, holding that there is no absolute bar to trademarking color alone.<sup>169</sup> Qualitex deemed the green-gold color for dry cleaning press pads, which had acquired sufficient

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<sup>165</sup>*Id.* at 223 (disagreeing with the ramifications of color protection in *Campbell Soup*, 175 F.2d at 798).

<sup>166</sup>*Id.* at 223-224.

<sup>167</sup>*Id.* at 223-224 (referencing *In re Hodes-Lange Corp.*, 167 U.S.P.Q. 255 (T.T.A.B. 1987) (weighing a “brilliant yellow” band versus a “bronzy gold” band); *Amsted Indus., Inc v. West Coast Wire Rope & Rigging, Inc.*, 2 U.S.P.Q. 1755 (T.T.A.B. 1987) (comparing two strands of “yellow” wire rope to two strands of “yellow and yellowish-green”).

<sup>168</sup>*Cf. NutraSweet*, 917 F.2d at 1027 (citing *Owens-Corning Fiberglas Corp.*, 774 F.2d at 1128) (sympathizing with the dissent’s assertion that “the overall color of a product cannot be a trade identity designation, nor is it entitled to registration.”) and *Master Distributors*, 986 F.2d at 224 (agreeing with *Owens-Corning* and “declining to establish a per se prohibition against protecting color alone as a trademark”).

<sup>169</sup>514 U.S. at 162.

secondary meaning, to be a source-identifying symbol worthy of trademark protection.<sup>170</sup> With its unanimous decision, the Supreme Court sent a strong, clear message: color can and should be trademarked where all statutory requirements have been met.

As in *Owens-Corning* and *Master Distributors*, *Qualitex* rejected the theoretical arguments against color alone trademarks. Finding color marks to be no different, inherently, than any other type of mark, the court noted that, “[i]t is the source-distinguishing ability of a mark – not its ontological status as color, shape, fragrance, word, or sign – that permits it to serve these basic purposes.”<sup>171</sup> The court’s determination that color trademarks should not be subjected to a heightened standard of review effectively rejects the color depletion and shade confusion arguments. Courts cannot consider availability of alternative colors any more than they worry about the availability of alternative words and the threshold for a likelihood of confusion must remain the same whether the court is considering shades of colors or word pronunciations.

In *Qualitex*, the color depletion theory was specifically dismissed as “unpersuasive” on the basis that the threat of color scarcity is relatively small.<sup>172</sup> The theory’s resulting ban on color trademarks simply would be an alarmist reaction to a rare problem that would anyway be prevented by the non-functionality requirement.<sup>173</sup> In other words, if the exclusive right to use a color mark severely hindered competition because no other viable colors were available, a color would be seen as serving a non-trademark function and could thus fail to receive trademark protection. Under the court-advocated system of case-by-case analysis, rather than a general prohibition of color trademarks, the presiding court would have authority to deny protection to any mark which threatened to grant the trademark holder monopoly powers. As for the concern that courts would not be able to properly assess the likelihood of confusion between shades due to differences in

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<sup>170</sup>*Id.* at 166, 174.

<sup>171</sup>*Id.* at 163.

<sup>172</sup>*Id.* at 168.

<sup>173</sup>*Id.* at 169.

lighting, *Qualitex* suggested that courts mimic the lighting conditions under which a product is generally sold.<sup>174</sup>

#### IV. Post-*Qualitex*: Reactions and Ramifications

Although clearly establishing that color alone can be protected when all other statutory requirements are met, *Qualitex* left open to interpretation exactly what these requirements demanded. Consequently, *Qualitex* has been widely scrutinized, with courts and legal scholars offering interpretations of the requisite distinctiveness and functionality, reassertions of the shade confusion theory, as well as hypotheses on the future course of single-feature, non-traditional trademark doctrine in light of this decision.

##### A. Secondary Meaning Revisited

The Supreme Court sidestepped the issue of whether or not a color could be inherently distinctive – and thus not require a showing of secondary meaning.<sup>175</sup> The court’s acknowledgement that “a product’s color is unlike “fanciful,” “arbitrary,” or “suggestive” words or designs, which almost *automatically* tell a customer

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<sup>174</sup>*Id.* at 167-168 (citing cases where such lighting re-enactments have already been carried out for assessing the likelihood of confusion for trademarks consisting of a color plus a design).

<sup>175</sup>*Qualitex*, 514 U.S. at 169 (noting only that “[w]e cannot find in the basic objectives of trademark law any obvious theoretical objection to the use of color alone as a trademark, where that color has attained ‘secondary meaning’ and therefore identifies and distinguishes a particular brand . . .”).

that they refer to a brand,” suggests that secondary meaning would be necessary to receive trademark protection.<sup>176</sup> Several courts have since read *Qualitex* to call for a showing of secondary meaning for color marks,<sup>177</sup> as has a Senior Examining Attorney with the PTO.<sup>178</sup> However, no such requirement was explicitly stated, and at least one scholar has asserted that color alone marks can be inherently distinctive if the use of the color is sufficiently unusual.<sup>179</sup>

## B. Aesthetic Functionality

*Qualitex* also added a new facet to the assessment of a mark’s functionality. Instead of creating an absolute bar to color marks that serve a non-trademark function, the court noted that:

where a color serves a significant nontrademark function – whether to distinguish a heart pill from a digestive medicine . . . – courts will examine whether its use as a mark would permit one competitor (or a group) to interfere with legitimate (nontrademark-related) competition through actual or potential exclusive use of an important product ingredient.<sup>180</sup>

Later, in 2001, the Supreme Court limited the application of the competitive need analysis to cases of aesthetic functionality.<sup>181</sup> For all other functions, such as being essential to the product’s use or affecting the cost or quality of the product, the *Inwood* standard remains in place.<sup>182</sup> Consequently, the PTO’s analysis

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<sup>176</sup>*Id.* at 162-163.

<sup>177</sup>See *Mana Prods., Inc. v. Columbia Cosmetics Mfg., Inc.*, 65 F.3d 1063, 1071 (2<sup>nd</sup> Cir. 1995); *Fabrication Enters., Inc. v. Hygenic Corp.*, 64 F.3d 53, 58 n.3 (2<sup>nd</sup> Cir. 1995); *Forschner Group v. Arrow Trading*, 124 F.3d 402 (2<sup>nd</sup> Cir. 1997); *Sazerac Co. v. Skyy Spirits, Inc.*, 37 U.S.P.Q.2d (BNA) 1731, 1733 (E.D. La. 1995).

<sup>178</sup>See Faye M. Hammersley, *Comment: The Smell of Success: Trade Dress Protection for Scent Marks*, 2 MARQ. INTELL. PROP. L. REV. 105, 143 (1998) (citing a telephone interview with an anonymous Examining Attorney, PTO (Oct. 30, 1997)).

<sup>179</sup>Schwartz, *supra* note 145, at 94-95 (citing purple peanuts as an example of a disjunctive use of color that could be considered inherently distinctive); see also Hammersley, *supra* note 178, at 145 (suggesting that color and scent marks can be viewed as inherently distinctive if analyzed under trade dress law).

<sup>181</sup>*TraFFix Devices, Inc. v. Mktg. Displays, Inc.*, 532 U.S. 23, 33 (2001). See *infra* notes 184-186 and accompanying text.

<sup>182</sup>*Id.* (quoting *Inwood*, 456 U.S. at 850, n. 10); see *supra* note 59 and accompanying text.

of an application for registration of a color alone trademark, with an aesthetic function, now includes the additional determination of whether or not this function would hinder competition.<sup>183</sup> *Qualitex's* aesthetic functionality analysis, that protection will be barred for a color functioning only to be aesthetically pleasing if this color is necessary to compete effectively,<sup>184</sup> has also been criticized. Although this idea allays fears of color depletion, the aesthetic functionality doctrine had previously been disfavored among courts.<sup>185</sup> Consequently, *Qualitex* was criticized for “breathing new life into a once dying doctrine,” under which “no trademark holder can feel safe.”<sup>186</sup> Others have taken issue with this functionality analysis, claiming that the psychological effects colors have on consumers are strong, but not easily recognizable by the courts or even the consumers, themselves.<sup>187</sup>

### C. Shade Confusion Reasserted

Some members of the legal community strongly oppose the court’s rejection of shade confusion, but many of the revamped theoretical arguments remain unconvincing. One legal scholar reemphasized the concern

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<sup>183</sup>*Cf.* Vana, *supra* note 141, at 395 (predicting that “nearly all color applications will require analysis of the ‘competitive effect’ factor”).

<sup>184</sup>514 U.S. at 169.

<sup>185</sup>Daniel C. Huddock, *Notes and Comments: Qualitex Co. v. Jacobson Products Co.: Color Receives Trademark Protection and the Courts Receive Confusion*, 16 J.L. & COM. 139, 152 (Fall, 1996) (citing the Third Circuit’s disdain for the doctrine because “the more appealing the design, the less protection it would receive.” *Keene Corp. v. Paraflex Industries, Inc.*, 653 F.2d 822, 825 (3<sup>rd</sup> Cir. 1981) quoted in 1 J. Thomas McCarthy, *McCarthy’s on Trademarks and Unfair Competition* §7.26[4][b], at 7-151).

<sup>186</sup>*Id.* at 152, 153.

<sup>187</sup>*See* Elizabeth A. Overcamp, *Recent Developments: The Qualitex Monster: The Color Trademark Disaster*, 2 J. INTELL. PROP. L.J. 595, 616-619 (Spring, 1995). *But see supra* notes 43-48 and accompanying text.

over shade confusion, noting that the process of differentiating between shades of a color is different in the judge’s chamber “where a judge may pore over swatches of color” from the actual purchase situation where “consumers are often rushed or unwilling to make a detailed analysis of a product’s appearance.”<sup>188</sup> However, this same rationale could be applied to any type of likelihood of confusion consideration: perhaps judges “pore over” the similarity in sounds of two words to a greater extent than does the purchasing public, but this does not therefore imply that courts should abstain from such analysis. *Qualitex*’s suggestion that courts re-create a store’s lighting conditions to portray the color marks more accurately has also been criticized because store lighting can vary by time of day, type of store, etc.<sup>189</sup> Again, this critique fails to take into account that perception of colors, symbols, sounds, is, by nature, subjective. Following this line of reasoning, courts should decline to determine the likelihood of confusion between words because pronunciations will vary according to the speaker’s voice and inflection. Finally, scholars contend that because trademark registrations are printed in black and white, with only eight available code linings for colors, courts are likely to be overly generous in determining the limits on confusingly similar colors.<sup>190</sup> Yet, courts have managed to consider color in combination with other features,<sup>191</sup> where the color registration process is no different. There are also several generally accepted alternative, more descriptive methods of describing color.<sup>192</sup> In the end, the assertion that as a result of color alone protection, the “finder of fact will be laden with subjectivity”<sup>193</sup> holds

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<sup>188</sup>Huddock, *supra* note 185, at 149.

<sup>189</sup>*See Overcamp, supra* note 187, at 615-616.

<sup>190</sup>Kearns, *supra* note 141, at 352-353.

<sup>191</sup>*See, e.g.,* *Mishawaka Rubber & Woolen Mfg Co. v. S.S. Kresge Co.*, 119 F.2d 316 (6<sup>th</sup> Cir.), *rev’d on other grounds* 316 U.S. 302 (1942); *Hygienic Products Co. v. Coe*, 85 F.2d 264 (D.C. Cir. 1936); *Layton Pure Food Co. v. Church & Dwight Co.*, 182 F. 24 (8<sup>th</sup> Cir. 1910); *Barbasol Co. v. Jacobs*, 160 F.2d 336 (7<sup>th</sup> Cir. 1947).

<sup>192</sup>*See Cooper, supra* note 124, at 5 n.20 (referring to the ISCC-NBS method of designating colors by exact shade, the Munsell system of describing colors by hue, value, and chroma, and the Ostwald system of specifying colors by hue and color/black/white content).

<sup>193</sup>Huddock, *supra* note 185, at 150.

no more weight for color marks than for any others.<sup>194</sup>

#### D. Scent

The approval of color alone protection under *Qualitex* should bolster the case for protection of other single-aspect non-verbal trademarks, such as scent. Before the Supreme Court handed down *Qualitex*, the T.T.A.B. accepted the registration of the plumeria scent mark for sewing thread and embroidery yarn, with a sufficient showing of secondary meaning.<sup>195</sup> The PTO's recognition of scent marks was limited, precluding protection for a fragrance that is a main feature of the product in question, such as perfume.<sup>196</sup> As a protected mark must create a unique association between the scent and that particular product, a fragrance can be registered only if it is not normally associated with the item in question.<sup>197</sup> Scent marks should be protected because they are effective source indicators. Studies have shown that the human memory is receptive to fragrant experiences, but this memory can only be conjured when a smell is re-experienced.<sup>198</sup> As a result, "when many people think they are recalling odors, they are actually thinking of 'some object associated with an odor. . .,'"<sup>199</sup> thus making scents quintessential source-indicators and prime candidates for trademark protection. Trademark protection is also expected to benefit the public by allowing manufacturers of scented products to protect their goodwill, prevent free-riding, and reduce consumer search costs for these uniquely

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<sup>194</sup>Interestingly, French law allows for the protection of distinctive shades of color alone marks, including "bright violet rubber bulbs for automobile horns, sky blue gasoline, antique pink yeast bags, and blue-grey rubber stoppers. Cooper, *supra* note 124, at 23.

<sup>195</sup>*In re Celia Clarke*, 17 U.S.P.Q.2d (BNA) 1238 (T.T.A.B. 1990).

<sup>196</sup>*Id.*

<sup>197</sup>Hammersley, *supra* note 178, at 127.

<sup>198</sup>*Id.* at 128 (citing Trygg Engen, *Odor Sensation and Memory* 5 (1991)).

<sup>199</sup>*Id.*



recognizable products.<sup>200</sup> Although scent mark registrations can be opposed on the grounds of functionality, application of the *Qualitex* holding will demonstrate that such marks can be protected. If a particular scent is essential to the use of the product, courts will deny protection, but if the scent merely adds aesthetic appeal, then protection will be precluded only when competition would be impaired significantly.<sup>201</sup> As there are a plethora of available alternative scents,<sup>202</sup> trademark protection of an individual scent is unlikely to hinder competition.

Critics of scent protection may assert versions of the shade confusion argument, but *Qualitex*'s rejection of the color arguments should similarly limit their persuasiveness in this context. The lack of an official classification system and the subjective nature of scent perception lay the groundwork for a shade confusion argument.<sup>203</sup> Yet the *Qualitex* finding that color marks are no more difficult to analyze than words or symbols,<sup>204</sup> renders moot this assertion with respect to scents.<sup>205</sup> Despite the newly expansive reach of trademark protection, registration of scent marks in the U.S. has been scarce. As of 1998, three years after *Qualitex* was decided, only eight trademark applications had been filed for scent marks.<sup>206</sup> Schering-Plough has considered pursuing common law trademark protection for its unique scent of Coppertone sunscreen, but it has declined to register this scent.<sup>207</sup> However, fragrance mark applications are numerous in the United

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<sup>200</sup>*Id.* at 129.

<sup>201</sup>*See supra* notes 180-183 and accompanying text. *See also id.* at 135-137 (positing that protection of a pine or lemon scented household cleaning product would hamper competition – and thus be denied protection, whereas a licorice scented version of the same product would be sufficiently distinctive that it would not impede on competition).

<sup>202</sup>*See* Hammersley, *supra* note 178, at 138.

<sup>203</sup>*See* Hammersley, *supra* note 178, at 150.

<sup>204</sup>*See supra* notes 170-171, 188-194 and accompanying text.

<sup>205</sup>*See* Hammersley, *supra* note 178, at 150.

<sup>206</sup>*Id.* at 105, n. 4, 127 (referring to applications for a lemon scent for a digital laser printer; cherry, almond, tutti-frutti, citrus, bubble gum, and strawberry for fuel additives; and an apple scent for an animal bit).

<sup>207</sup>Telephone Interview with Joel Wiener, Senior Director, Trademark and Copyrights, Schering-Plough Corp. (Feb. 5, 2003).

Kingdom, where the Trade Mark Registry is sympathetic to scent protection,<sup>208</sup> and this trend may soon catch on in the United States, as well.

#### D. Flavor Marks

The rising trend of color alone and scent alone marks may also lend credence to the notion that flavor alone marks should be protected, and distinguishing flavors, as opposed to scents, are likely to be used by pharmaceutical companies. The Supreme Court precluded protection for chocolate flavored quinine in 1924,<sup>209</sup> but courts have not revisited this issue since *Qualitex*. Since the general trend in trademark law has been to extend the bounds of trademark law, and now that single-sense marks, such as color alone, have been upheld, flavor protection is not unlikely.<sup>210</sup> That pharmaceutical companies have begun to pursue trademark protection for flavor marks is the most compelling evidence that the bounds of protection may soon be extended. In France, Eli Lilly has applied to register the strawberry-like taste of a popular French candy for the liquid form of Seclor.<sup>211</sup> While it has been suggested that the subjectivity in flavor perception weighs against flavor protection,<sup>212</sup> similar counter-arguments to those used with respect to color and scent protection can overcome this assertion; courts could reason that since all sensory perceptions are subjective, this assertion is not sufficiently compelling.<sup>213</sup>

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<sup>208</sup>Hammersley, *supra* note 178, at 151-153.

<sup>209</sup>*William R. Warner & Co.*, 265 U.S. at 529.

<sup>210</sup>See Hammersley, *supra* note 178, at 121-122 (suggesting that “future [flavor mark] applicants can use successful arguments for color and scent registration and apply them to advocate flavor marks registrability”).

<sup>211</sup>Telephone Interview with Robert E. Lee, Jr., Asst. Gen. Pat. Coun., Law Div., Eli Lilly & Co. (Jan. 3, 2003). Although Eli Lilly intends to abandon this application due to cost-cutting and decreased emphasis on the particular drug involved, protection may continue to be pursued if taken on as a pro-bono matter.

<sup>212</sup>See Nancy L. Clarke, *Note: Issues in the Federal Registration of Flavors as Trademarks for Pharmaceutical Products*, 1993 U. ILL. L. REV. 105, 127, 131 (1993).

<sup>213</sup>See *supra* notes 188-194 and accompanying text.

Flavor marks must also avoid functionality hurdles in order to be protected. A flavor's ability to mask a drug's natural flavor may not necessarily bar protection. If the original flavor is truly unpalatable, then a flavor mark will be deemed functional under the utilitarian functionality doctrine,<sup>214</sup> despite the availability of alternative flavors.<sup>215</sup> However, if the original flavor is simply medicinal, albeit unpleasant, the added flavor's enhancement of taste could be viewed as a form of aesthetic functionality; the flavor makes a consumer's experience more pleasurable than it would be otherwise. Consequently, if there are feasible flavor alternatives that could also mask the natural flavor,<sup>216</sup> and if the exclusive right to use the flavor in question would not significantly strain competition, then under the *Qualitex* rationale, protection would remain available.<sup>217</sup> The theory that for flavor mark analyses, aesthetic functionality merges with utilitarian functionality because palatable flavors can increase patient compliance<sup>218</sup> is, itself, unpalatable. Patients' flavor preferences vary, making it unlikely that a doctor would be able to predict which flavor, among several palatable alternatives,<sup>219</sup> would most likely increase compliance. Assertions of flavor functionality for creating a placebo effect<sup>220</sup> or for serving as a particular suspension medium<sup>221</sup> may, however, be more difficult to

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<sup>214</sup> See Clarke, *supra* note 212, at 128. (citing H.C. Ansel, Introduction to Pharmaceutical Dosage Forms 67 (1959)).

<sup>215</sup> Assessments of utilitarian functionality do not take into account competitive need. See *supra* notes 35, 59, 180-182 and accompanying text.

<sup>216</sup> The availability of alternatives seems likely since thousands of flavors exist. See, e.g., 21 CFR 172.510 (2003) for a list of over one hundred natural flavoring substances and food additives permitted for direct addition to food for human consumption.

<sup>217</sup> See *supra* notes 180-181, 183 and accompanying text.

<sup>218</sup> See Clarke, *supra* note 212 at 130.

<sup>219</sup> In order to qualify for protection, more than one such flavor must be possible. See *supra* notes 180-181, 183 and accompanying text.

<sup>220</sup> *Id.* at 129 (citing A. Leslie, Ethics and Practice of Placebo Therapy, AM. J. MED. 854, 859 (1954) that "people tend to be skeptical of medications that do not look, taste, or smell like 'medicine.'").

<sup>221</sup> See *William R. Warner & Co.*, 265 U.S. at 531; Clarke, *supra* note 212, at 129-130.

defeat.<sup>222</sup>

## E. Liquid Medications

Strong opposition has been voiced against color alone protection in liquid medications despite *Qualitex*, but protection for colored liquids may still be attainable. Historically, courts have denied trademark protection to colored liquids.<sup>223</sup> Since liquids cannot have patterns or other variations of single colors, the color depletion argument may be somewhat more compelling in this context:

When a liquid is colored, the configuration of the color is necessarily ‘solid,’ ‘applied all over,’ and ‘without variation.’ . . . With respect to colors of liquids, there truly is a relatively limited number of arrangements available, and removing one could unduly handicap competitors. Colors of liquids, therefore, may be the only context in which the ‘color depletion’ argument has some merit and viability.<sup>224</sup>

Moreover, if the availability of different-colored liquids is truly more limited than that of colored capsules and tablets, then exclusive use grants would also impede competition, and this protection would be barred under the *Qualitex* doctrine of aesthetic functionality.<sup>225</sup> However, the color alone protection permitted in *Qualitex* was not based on the wide variability of a color’s application, but instead on the availability of color alternatives.<sup>226</sup> Thus, as long as other ‘solid’ colors can replace the trademarked color of a liquid

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<sup>222</sup> See Clarke, *supra* note 212, at 128-130.

<sup>223</sup> See *Norwich Pharmacal*, 271 F.2d at 572 (denying protection to pink to liquid stomach medicine); *Warner Lambert*, 718 F. Supp. at 396 (denying protection to amber mouthwash); *William R. Warner & Co.*, 265 U.S. at 531-533 (denying protection to chocolate-flavored quinine).

<sup>225</sup> *Qualitex*, 514 U.S. at 169.

<sup>226</sup> *Id.* at 168.

medication,<sup>227</sup>this type of protection should not be denied.

V.

### Modern Practice of Brand Pharmaceuticals

The availability of trademark protection continues to increase and a few pharmaceutical manufacturers have begun to take advantage of the newly expanded trademark doctrine. AstraZeneca's publicity for its anti-ulcer medication as a "purple pill" epitomizes the type of trademark protection now available to pharmaceutical manufacturers. Introduced in 1989 to treat heartburn, purple Prilosec<sup>228</sup> was the best selling drug in the world in 2000.<sup>229</sup> Prilosec's longer-lasting replacement, Nexium, was also distributed in the same color and similarly promoted as the "purple pill" in both advertisements and on the website [www.purplepill.com](http://www.purplepill.com).<sup>230</sup> Consequently, AstraZeneca created a "purple brand" that "is even more important than the individual products that use it."<sup>231</sup> However, AstraZeneca's emphasis on product design is exceptional, rather than representative of industry practice. Overall, even though the current status of trade dress and trademark law for product design generally bodes well for brand name manufacturers, the prac-

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<sup>227</sup>See *supra*, note 165 and accompanying text for a discussion of the wide spectrum of colors.

<sup>228</sup>Note that Prilosec was marketed under the name Losec in some markets outside of the U.S..

<sup>229</sup>See *Pharma Brands Capture Hearts and Minds*, *supra* note 9; see also *All Things Considered*, National Public Radio (Apr. 18, 2002), <http://www.bamcoalition.org/News/HW/04.18.02.htm>.

<sup>230</sup>On the website, [www.purplepill.com](http://www.purplepill.com), viewers are urged to their doctors "about the Purple Pill called NEXIUM." The purple tablet is featured throughout, and as a user drags the mouse over the "About Nexium" page, the mouse's path is highlighted by a trail of purple tablets. <http://www.purplepill.com/about/20.aboutnexium.asp> (last visited Mar. 3, 2003). Information about Nexium's predecessor, Prilosec can be found at <http://www.priloseconline.com> (last visited Mar. 3, 2003).

<sup>231</sup>*Pharma Brands Capture Hearts and Minds*, *supra* note 9.

tice of trademarking individual design features and pursuing trade dress protection to preclude look-alike generics appears to be relatively rare. Examination of pharmaceutical companies' strategies and practices reveals that issues of timing, funding, chance recognition of the feature, as well as the potential for run-ins with other brand manufacturers, may influence manufacturers' decisions to publicize and protect distinctive design features of pharmaceuticals.

Proper pursuit of trademark and trade dress protection requires a significant amount of planning, and since the expanded trademark doctrine is relatively new, most pharmaceutical manufacturers may have simply missed the boat for their current products. A trademark attorney advised that:

To increase the likelihood of securing nontraditional trademarks for pharmaceuticals, the legal team in charge of intellectual property should coordinate with several other departments within the company to discuss and plan for a nontraditional trademark protection program. Specifically, the intellectual property team should develop a registration and enforcement strategy to maximize the value of the nontraditional mark by coordination with (1) manufacturing to prove non-functionality and build it into product planning; (2) regulatory to understand what brand signals will be encountered and used by patients, pharmacists and physicians; and (3) marketing to build nontraditional mark into advertising campaign and to include appropriate look for advertising.<sup>232</sup>

This process for securing protection should also be initiated "early in the product life cycle" and "well in advance of patent expiration."<sup>233</sup> Ideally, this strategy should begin during the clinical phase of a drug's development: once the naming process is complete, the conception of a drug's color, flavor, shape and overall product packaging should begin.<sup>234</sup> Yet, while strategic planning is clearly advantageous, in some instances, protection may be achieved without it. AstraZeneca did not file for registration of the purple color of its Prilosec tablets until eleven years after the medication was introduced to the market.<sup>235</sup> Consequently, timing

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<sup>233</sup> *Id.*

<sup>234</sup> Telephone Interview with James L. Detorre, President and CEO, and Christopher Nikides, General Counsel, Brand Institute (Apr. 2, 2003).

<sup>235</sup> Reg. 76103792 to AstraZeneca filed on Aug. 4, 2000.

is probably not the most compelling explanation for manufacturers' hesitancy to protect pharmaceutical design features.

Money, however, is most likely a determining factor in whether or not trademark protection is sought. Although applications for trademark registration cost only about three hundred dollars, the marketing budget needed for a product to achieve secondary meaning can be quite substantial.<sup>236</sup> Moreover, even if pharmaceutical companies can afford to sufficiently promote a drug's unique features, they may choose to allocate this money for other types of marketing, such as informing the public about a drug's function.<sup>237</sup> Consequently, it is possible that product design features are promoted – and thus protected against copying – for only those drugs whose primary function is already commonly known, such as Tylenol.<sup>238</sup> This theory may shed light on why Viagra's design, the “little blue friend”<sup>239</sup> was heavily promoted, as well. Along with the common knowledge explanation, the focus on appearance over function has also been attributed to a rise in popularity of “lifestyle drugs.”<sup>240</sup> Since drugs such as Prozac, Viagra and Xenical remedy “conditions hitherto not considered as true ‘diseases,’” building brand association through appearance may take precedence over publicizing the function of a, perhaps, non-essential remedy.<sup>241</sup> The attention given to Valium's distinctive shape, V-shaped perforations within a round, flat-faced tablet, might also lend credence to the lifestyle drug

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<sup>236</sup>Telephone Interview with Larry Rickles, Trademark Attorney, Johnson & Johnson Co. (Jan. 3, 2003); *see supra* notes 20-28 and accompanying text for a discussion of expenditures sufficient to show secondary meaning has been acquired; *see supra* notes 18-19, 175-179 and accompanying text for a discussion of when secondary meaning is required.

<sup>237</sup>Telephone Interview with Larry Rickles, *supra* note 236.

<sup>238</sup>*Id.*; *see McNeil*, 919 F. Supp. at 202, 205 (finding that the Tylenol manufacturer's promotion of the red and yellow gelcaps would likely be sufficient to show secondary meaning at trial, and ordering a preliminary injunction against defendant manufacturer of a look-alike generic).

<sup>239</sup>Former Senator and presidential candidate Bob Dole appeared in television commercials for Viagra, referring to it as his “little blue friend.” *See Pharma Brands Capture Hearts and Minds*, *supra* note 9.

<sup>240</sup>*Pharma Brands Capture Hearts and Minds*, *supra* note 9.

<sup>241</sup>*Id.*

theory. It is also possible that promotion efforts for drugs such as Viagra focus on design, rather than function because the related medical condition is a quite sensitive topic.<sup>242</sup> In addition, pharmaceutical companies may also focus on design features where a prescription product is expected to be switched to OTC status in the future, so that consumers will remain loyal to the brand version when choosing medication on their own. In sum, under any of these scenarios, more funding is available for the promotion of a drug's design since less money is allocated for publicity concerning the drug's function.

Public acceptance of a particular design also factors into the amount of attention brand manufacturers devote to design protection. Certainly, concentrating on a particular design feature of a medication prescribed only for terminally ill patients in the end stages of their malady would be ineffective and thus unlikely. In contrast, other drugs have received so much publicity, that their design features have become source indicators by accident. When first introduced, Prozac's manufacturer, Eli Lilly & Co., did not intend to register Prozac's green and cream color combination.<sup>243</sup> However, as Prozac became widely-recognized and received great publicity, the green and cream colors surfaced on the covers of books and magazines referring to Prozac. According to an in-house trademark attorney, Eli Lilly then realized that this color combination had become an "alter ego" of the brand name and filed for registration of the combination in 1996.<sup>244</sup> However, as the Prozac phenomenon is probably exceptional, rather than a common occurrence, manufacturers should conduct consumer research surveys to document the levels of brand recognition associated with specific design features.

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<sup>242</sup>Pfizer, the manufacturer of Viagra, could not be reached for comment.

<sup>243</sup>Telephone Interview with Robert E. Lee, Jr., *supra* note 211.

<sup>244</sup>*Id.*



Perhaps the current strength of the trademark and trade dress doctrine suffices to dissuade generic manufacturers from copying pharmaceutical product design, lessening the need for brands to be aggressive in seeking protection. Losing the battle over a particular color can be costly for a generic manufacturer even above the costs of legal fees and/or damage awards; if a generic manufacturer receives FDA approval for a look-alike medication with certain color dyes and is subsequently barred from manufacturing the drug in that color, then the generic must seek FDA re-approval for the drug's different color additives before being able to reenter the market.<sup>245</sup> As a result, the fewer look-alikes produced, the less incentive brand manufacturers have to register such marks and the fewer cases that arise claiming look-alike trademark and trade dress infringement. Moreover, even if generic manufacturers do engage in such copying, they may be more willing to settle out of court because of the present state of the law.

Brand manufacturers seeking protection may also encounter opposition from other leading companies in the industry, and perhaps this a stronger deterrent than the threat of battling against a generic. Although the evolution of trademark protection is generally thought of as a struggle between brand and generic manufacturers, brand name competitors will also contest any assertion of ownership that they fear will impede their ability to compete in the marketplace. Brand versus brand clashes are also less predictable because brands that contest certain marks, themselves seek trademark protection for other design features. For example, Schering-Plough has both aggressively pursued trademark protection for some of its own designs and actively challenged other companies' attempts to receive protection.<sup>246</sup> While Schering-Plough has filed for trademark protection of its unique color combinations and tablet designs,<sup>247</sup> it has taken the

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<sup>245</sup> *Id.*

<sup>246</sup> Telephone Interview with Joel Wiener, *supra* note 207.

<sup>247</sup> *Id.* (noting Schering-Plough's trademark registrations for the "yellowish" canister with orange tip color combination of the Proventil inhaler, and for the rounded, multifaceted tablet design with a star cut-out).

position that trademarks should not be awarded for single color pharmaceutical products.<sup>248</sup> Schering-Plough also has an opposition pending against Smithkline Beecham's trademark application for the shape of a capsule with tapered ends for a drug called Diazide.<sup>249</sup> While this industry practice of selective approval for trademark protection could be a basis for criticizing pharmaceutical design protection, this additional hurdle to protection should probably be viewed as a further safeguard against superfluous protection. Each self-interested actor will, where economically feasible, aggressively pursue trademark protection, regardless of whether or not such protection is actually warranted. If all of the brand manufacturers joined forces to stretch trademark protection as far as possible, then there would be a risk – albeit small if the PTO and courts remain vigilant – that this powerful lobby might succeed in achieving improper protection. However, if each company seeking such protection must prevail over the protestations of both generic and other brand name competitors, then there should be no cartel-like influences on the outcome. Schering-Plough asserts that single colors for pharmaceutical products are not sufficiently distinctive, and company policy would change only if a color were “extremely unique” and heavily promoted.<sup>250</sup> In fact, these requirements are no different from those established in *Qualitex*,<sup>251</sup> and Schering-Plough's efforts to preclude protection of single colors that fail to meet these requirements simply helps assure that appropriate trademark protection boundaries remain in place. Individual brand manufacturers may appear to be drawing arbitrary lines in the sand, justifying trademark protection for those aspects which they deem important and criticizing awards of protection for those aspects which would only be beneficial to other members of the industry. Yet this lack of industry solidarity helps level the playing field between the brand name and generic manufacturers and

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<sup>248</sup>*Id.* (maintaining that single colors of pharmaceuticals are not distinctive and that patients rely on the pharmaceutical colors to identify the type of drug, rather than the manufacturer).

<sup>249</sup>*Id.*

<sup>250</sup>*Id.*

<sup>251</sup>*See supra* notes 171-173 and accompanying text; *see also supra* notes 175-179 and accompanying text for a discussion of whether or not color alone can be inherently distinctive.

allows only balanced protection to prevail.

## VI. Conclusion

A 1993 article in *Fortune* magazine simply stated that “generic [versions of brand name drugs] *can’t* come in capsules of the same size, shape, or color.”<sup>252</sup> Although this may be an overstatement, it accurately reflects the general sentiment that the law in this area strongly favors original manufacturers.

Trademark and trade dress law has evolved, becoming more sympathetic to the creators of original designs and more antagonistic towards those attempting to free-ride on a creator’s promotional efforts. To succeed in claims of unprivileged imitation, brand manufacturers must show secondary meaning, disprove opponents’ claims of functionality, and establish that copying will cause a likelihood of confusion. Brand manufacturers may also be able to pursue vicarious liability for pharmacists’ passing off look-alikes. Moreover, in some instances, brand manufacturers can win a preliminary injunction against look-alike generics if there is sufficient evidence that the trade dress originator would be irreparably harmed, that the balance of equities weighs in favor of the movant, and that the public would thereby be best served. Finally, the Supreme Court’s approval of a color alone trademark reinforced this trend and should encourage more pharmaceutical manufacturers to take advantage of this doctrine where all statutory requirements have been met.

As with any other type of investment, money should be allocated based on expected income. Investments should be made where there is the most to gain and product design can create promising returns. Building brand recognition not only builds market share, but may also help shield brand manufacturers against liability for problems caused by generic versions of the same drug. In fact, the costs associated with liability are so

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<sup>252</sup>Tully, *supra* note 2. Emphasis added.

high, that some generic manufacturers are working to differentiate themselves from brand products to reduce the risk of legal problems arising from branded products.<sup>253</sup> While trademark protection is not yet being utilized to its full potential, more research is being conducted on pharmaceutical product design than ever before.<sup>254</sup> Although emphasis on pharmaceutical product design may have been confined to lifestyle drugs or other specific categories in the past, the increasing competitiveness of the industry as well as the risks of misplaced liability and infringement suits make product design important for all drugs.<sup>255</sup> Pharmaceutical product design will only increase in importance in the future and manufacturers who fail to pursue branding through distinctive coloring, shaping, and flavoring will be at a significant disadvantage.

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<sup>253</sup>Telephone Interview with James L. Detorre and Christopher Nikides, *supra* note 234.

<sup>254</sup>*Id.*

<sup>255</sup>*Id.*